
From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/12/2020 1:28:19 AM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: YOUR INPUT NEEDED: ACTIV Web Content
Attachments: Combined Comments for ACTIV Web page 921PM.docx

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 8:53 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: YOUR INPUT NEEDED: ACTIV Web Content

Sorry ignore last email- this is the updated.

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health



OSP Blog: [Under the Poliscopes](#)
Twitter: @CWolinetzNIH

From: Brodd, Lauren (NIH/OD) [E]
Sent: Monday, May 11, 2020 8:52 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: YOUR INPUT NEEDED: ACTIV Web Content

Updated attached.

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health



OSP Blog: [Under the Poliscopes](#)
Twitter: @CWolinetzNIH

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 8:15 PM

To: Brodd, Lauren (NIH/OD) [E] [b6]

Subject: RE: YOUR INPUT NEEDED: ACTIV Web Content

Hi Lauren,

Please see attached edited and clean versions.

Thanks,
Ashley

From: Brodd, Lauren (NIH/OD) [E] [b6]

Sent: Monday, May 11, 2020 6:43 PM

To: Parker, Ashley (NIH/OD) [E] [b6]

Subject: RE: YOUR INPUT NEEDED: ACTIV Web Content

Attached updated version of our document.

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health



OSP Blog: [Under the Poliscope](#)

Twitter: @CWolinetzNIH

From: Brodd, Lauren (NIH/OD) [E]

Sent: Monday, May 11, 2020 6:28 PM

To: Parker, Ashley (NIH/OD) [E] [b6]

Subject: RE: YOUR INPUT NEEDED: ACTIV Web Content

Hi Ashley,

I took a look at this and made some edits. Depending on the timing this is needed, I would be happy to review again and make additional changes but I wanted to get your initial thoughts first. Do you want to chat to discuss this? My number is [b6] if that would be easiest.

Thanks,

Lauren

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health



OSP Blog: [Under the Poliscopes](#)

Twitter: @CWolinetzNIH

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 5:17 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: FW: YOUR INPUT NEEDED: ACTIV Web Content

From: Meltzer, Abbey (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 11:42 AM
To: Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Gorman, Greta (FNIH) [T] [b6]
Subject: RE: YOUR INPUT NEEDED: ACTIV Web Content

Maria and David,

We wanted to let you know that we have updated the Working Group rosters so they should be ready for public consumption now (see attached). We also created a roster for the Executive Committee. If you agree, we can share the WG rosters with the WG leads and let them know that we will be passing these on to NIH for the ACTIV webpage.

Is there any other content you recommend we share with NIH for adding to the webpage (they are asking particularly if we have info about frequency of meetings, agendas, anything to show work is underway)?

Please let me know if we can help with anything else.

Best,
Abbey

From: Meltzer, Abbey (FNIH) [T]
Sent: Friday, May 8, 2020 12:35 PM
To: Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Gorman, Greta (FNIH) [T] [b6]
Subject: FW: YOUR INPUT NEEDED: ACTIV Web Content
Importance: High

Maria and David,

Please see the email below from Renate regarding the ACTIV webpage (and attached webpage).

I noticed that they include the Executive Committee here (and not the Leadership Group) as well as are asking for agendas, summaries, etc. that could show work is underway. What are your thoughts on including any of those things? And do we have anything high-level enough to include, such as we did in the past with HEAL?

Greta and I culled together working group rosters for publication on the website using the notes provided by the working group leads. We cleaned up the notes we were given (e.g. added degrees, formalized institutional names when those were abbreviated, etc.), but we may want to run these rosters by the leads before the information is formally published in case any of membership changed in the past few days. I have attached the WG rosters for your reference.

APAR0000013450

Let me know if you want to discuss.

Best,
Abbey

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Friday, May 8, 2020 11:07 AM

To: Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]

Wojtowicz, Emma (NIH/OD) [E] [b6]

Subject: YOUR INPUT NEEDED: ACTIV Web Content

Importance: High

Hi Abbey and Greta:

Attached is draft web content for a new ACTIV page. Would you review it and add necessary information (like Exec Committee and Working Group names) and other missing information? I would also love to have David review it and see if we can put a bit more meat to these bones. We'd love to try to get the page launched on Monday or Tuesday next week, so I would be grateful for your input as soon as possible.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/12/2020 2:04:26 AM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: Fwd: YOUR INPUT NEEDED: ACTIV Web Content
Attachments: NIH OCPL_ACTIV webpage content_5_7_2020.docx; ATT00001.htm; Therapeutics-- Preclinical Working Group.docx; ATT00002.htm; Clinical Trial Capacity Working Group.docx; ATT00003.htm; Vaccines Working Group.docx; ATT00004.htm; Therapeutics--Clinical Working Group.docx; ATT00005.htm; ACTIV Executive Committee.docx; ATT00006.htm

Ashley Parker, Ph.D.
Special Assistant to Acting Chief of Staff to the NIH Director
Office of the Director | National Institutes of Health
Tel: [b6]

Begin forwarded message:

From: "Wholley, David (FNIH) [T]" [b6]
Date: May 11, 2020 at 5:01:42 PM EDT
To: "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: YOUR INPUT NEEDED: ACTIV Web Content

From: Meltzer, Abbey (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 11:42 AM
To: Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Gorman, Greta (FNIH) [T] [b6]
Subject: RE: YOUR INPUT NEEDED: ACTIV Web Content

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Best,
Abbey

From: Meltzer, Abbey (FNIH) [T]
Sent: Friday, May 8, 2020 12:35 PM

APAR0000013454

To: Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Gorman, Greta (FNIH) [T] [b6]
Subject: FW: YOUR INPUT NEEDED: ACTIV Web Content
Importance: High

Maria and David,

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I noticed that they include the Executive Committee here (and not the Leadership Group) as well as are asking for agendas, summaries, etc. that could show work is underway. What are your thoughts on including any of those things? And do we have anything high-level enough to include, such as we did in the past with HEAL?

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Let me know if you want to discuss.

Best,
Abbey

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Friday, May 8, 2020 11:07 AM
To: Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]
Subject: YOUR INPUT NEEDED: ACTIV Web Content
Importance: High

Hi Abbey and Greta:

Attached is draft web content for a new ACTIV page. Would you review it and add necessary information (like Exec Committee and Working Group names) and other missing information? I would also love to have David review it and see if we can put a bit more meat to these bones. We'd love to try to get the page launched on Monday or Tuesday next week, so I would be grateful for your input as soon as possible.

Thanks,
Renate

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/5/2021 11:45:16 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Koniges, Ursula (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5ae2c3139654bc0b9b95718d516310b-konigesum]
Subject: RE: DDRMS for COS
Attachments: WF 397560 - Selected documents from Incoming folder

One more FYI that came in today: WF3975620-National Colorectal Cancer Awareness Month, March 2021 attached.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, February 5, 2021 3:56 PM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Koniges, Ursula (NIH/OD) [E] [b6]
Subject: Re: DDRMS for COS | Attn: Weekly Cabinet Report Submission Due by 3PM TODAY

Thanks, Carrie!

Ashley

On Feb 5, 2021, at 1:56 PM, Wolinetz, Carrie (NIH/OD) [E] [b6] wrote:

See below

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, February 5, 2021 12:03 PM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Koniges, Ursula (NIH/OD) [E] [b6]
Subject: RE: DDRMS for COS | Attn: Weekly Cabinet Report Submission Due by 3PM TODAY

Oops! Plus the last attached FYI.

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, February 5, 2021 12:01 PM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Koniges, Ursula (NIH/OD) [E] [b6]
Subject: DDRMS for COS | Attn: Weekly Cabinet Report Submission Due by 3PM TODAY

Hi Carrie,

Please see DDRMS below separated by actions vs. FYI's. **ES has requested any submissions for the weekly Cabinet Report on behalf of COS by 3pm today.**

Need Your Recommendation

WF397483-REMARK: Vetting Request for CoS (ATTN: Dr. Wolinetz) Please review the attached invitation from Emily Chin of the Student Osteopathic Medical Association (SOMA) inviting him to participate as a speaker during their Virtual Spring Convention on Saturday, March 6. **ES sought vetting advice from NIAMS and OCPL; we have not yet received NIAMS recommendation, however, John Burklow defers to your decision. Defer to the Director's preference**

WF397115- REMARK: Vetting Request for CoS (ATTN: Dr. Wolinetz) Dr. Collins received the attached invitation from Dr. Lee Fleisher, CMS Chief Medical Officer at the Centers for Medicare and Medicaid Services, inviting him to participate in the 2021 Virtual CMS Quality Conference on March 2-3. **We vetted with OCPL and John Burklow suggested that Dr. Collins appoint a surrogate, however, he did not identify one. ES wanted to check with you to see if you have a suggestion? Since he cited SCD, suggest that Gary Gibbons or Amy Patterson would be great alternates**

WF397455- REMARK: Vetting Request for Dr. Wolinetz. Please review the attached invitation and respond with your recommendation by February 4, 2021. **Dr. Lauer recommends declining (response attached).** ES will vet with OCPL to follow your recommendation. Agree, decline

WF397586- REMARK: Assigned to CoS (attn Ashley Parker) for necessary action. Writer from Gedeon Richter seeks advice from ACTIV regarding their SARS-CoV-2 therapeutic. **I recommend we have ES sent the standard language to direct companies to the ACTIV preclinical and clinical compound portal for their submission. It's fine to add a line item that says "if you have any questions regarding your submission or need additional information please contact activ_submission@fnih.org. That sounds like a good plan**

WF397573-REMARK: HHS Report: ES is issuing a recurring data call for the HHS Weekly Cabinet Report. Any items to report for COS? , due to ES by 3:00pm Friday, 2/5. See earlier grumpy note. ☹️

FYI's

WF397608- OS FYI: The Maryland Congressional Delegation writes to Acting Secretary Norris Cochran and Chief Operating Officer of Operation Warp Speed (OWS) General Gustave Perna requesting that OWS support the Maryland Department of Health's request that the Federal Government aid with vaccine allocations for NIH.

WF397541- REMARK: Hello! ES sent the writer the standard portal acknowledgement.

WF397512- Drs. Rodriguez Vidigal and Barrantes Gallego wrote to Drs. Collins and Fauci to share their hypothesis that diminazene, not yet tested to combat COVID-19 might be an effective treatment for the coronavirus. REMARK: Hello! ES sent the writer the standard portal acknowledgement.

WF397467- Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking.

WF397567- REMARK: OS: Assigned to CoS and ADEPD as FYI. Assigned to NIAID, CC, ORS, OM, OHR, and OSP for clearance (DUE nlt 3:00pm today, 2/2) to review the strategy outline for Commissioned Corps and the COVID-19 Response, which is for a meeting tomorrow morning (document 1 in the Incoming folder).

WF397424- OS Clearance: Continued Activation of the U.S. Public Health Service Commissioned Corps for the COVID-19 Response

Thanks,

Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 8:38:07 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Declined: ACTIV and BayCare Health System (Florida)
Location: see webex below

Start: 5/15/2020 4:00:00 PM
End: 5/15/2020 4:30:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 8:36:16 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Thanks for confirming – I did not think so! 😊

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 4:36 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Karen said it isn't necessary for you to join call. So you can just decline the invite.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 4:28 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Thanks, Cheryl. Yes, it does but I did not think I needed to join the call but happy to join if David and Karen find it useful. Please let me know – thanks!

Ashley

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 3:46 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Question re: ACTIV and BayCare Health System (Florida)

Ashley

Does this time work for you? 12-12:30 May 15?

APAR0000013503

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

b6

fniih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fniih.org/pandemic



From: Lewandowski, Amie [b6]
Sent: Monday, May 11, 2020 3:19 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Mauck, Danielle [b6]; Higgins, Joni C. [b6]
Subject: Question re: ACTIV and BayCare Health System (Florida)

Hi Cheryl-

It looks like May 15th from 12pm to 1pm works well for Joni and Danielle.
Will you be sending out the invite with a call in number?

Thank you,

Make it a Great Day!

Amie Lewandowski
Administrative Assistant to Danielle Mauck, Director of Sponsored Programs and Research
Sponsored Programs and Research
2985 Drew Street, Clearwater, FL 33759
MS 1027, 3rd Floor

To: [b6]

[b6]

BayCare.org



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APAR0000013503

only. If you are not the addressee, any disclosure, copy, distribution or use of the contents of this message is prohibited. If you have received this electronic message in error, please notify the sender and destroy the original message and all copies.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 6:03:55 PM
To: Higgins, Joni C. [b6]
CC: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Hi Joni,

I am cc'ing Karen Tauntas and David Wholley with FNIH who are coordinating the efforts with ACTIV to find a time that best fits for you to speak with them.

Best,
Ashley

From: Higgins, Joni C. [b6]
Sent: Monday, May 11, 2020 1:32 PM
To: Parker, Ashley (NIH/OD) [E]; [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Ashley, thanks so much for your note. I appreciate the quick follow-up. Do you think a call at some point this week might be a possibility?

Joni

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 1:24 PM
To: Higgins, Joni C. [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)


WARNING: This email originated outside of BayCare. BE CAUTIOUS clicking links and opening attachments. Use the Report Phishing and Spam button to report malicious emails and contact the IS Service Desk with all other suspicious activity.

Hi Joni,

Thank you for sharing BayCare Health System's interest in becoming involved as a large non-profit hospital system with ACTIV. We are in the process of developing a portal to receive submissions from interested partners however in the meantime I am triaging these request for our working groups.

I've entered the information you've provided below into our database and will share this information with leads of our ACTIV clinical capacity working group to follow up with you.

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [REDACTED] b6
 National Institutes of Health

From: Higgins, Joni C. [REDACTED] b6
Sent: Monday, May 11, 2020 12:19 PM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Subject: Question re: ACTIV and BayCare Health System (Florida)

Hi, Ashley,

I am writing at the suggestion of House Energy & Commerce Committee staff, who suggested you would be a great person with whom to start with a brief question outlined below.

I lead federal advocacy for BayCare Health System, one of Florida's largest not-for-profit health systems, comprised of 15 hospitals and approximately 30,000 team members and physicians in West Central Florida (Tampa Bay area).

BayCare was glad to see last month's announcement regarding the creation of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership. As ACTIV continues its work, **is there someone on the team with whom we could speak about becoming involved as a large, not-for-profit hospital system in the State of Florida?**

We view this as a significant and very much needed development to help coordinate many different aspects of COVID-related research, and we would appreciate any insight you would have to connect with the group and its efforts.

Thanks so much,
Joni

Joni Higgins
Federal Government Relations Manager

BayCare Health System

[REDACTED] b6

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APAR0000013507

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 5:58:54 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Thanks Karen and David. I will pick up from the thread below and cc both of you for follow up to schedule a call.

Ashley

From: Tountas, Karen (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 1:55 PM
To: Wholley, David (FNIH) [T] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Thanks David. Our emails crossed...

As I said, if agreeable to both of you, I will contact them by email. I will add them to the list to bring forward to the CT Capacity WG.

K

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 1:47 PM
To: Parker, Ashley (NIH/OD) [E] [b6] Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Karen, I kind of think we should, if only to let them know what is going on as a courtesy. On the other hand you may want to handle this through your committee. I am happy to participate if the former. Thanks, Davdi

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 1:42 PM
To: Wholley, David (FNIH) [T] [b6] Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Would a call with BayCare Health be of interest? Leaving it to both of you to decide and follow up if interested.

Thanks,
Ashley

From: Higgins, Joni C. [b6]
Sent: Monday, May 11, 2020 1:32 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Ashley, thanks so much for your note. I appreciate the quick follow-up. Do you think a call at some point this week might be a possibility?

Joni

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 1:24 PM
To: Higgins, Joni C. [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

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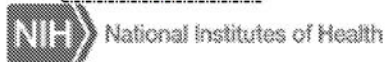
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Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]



From: Higgins, Joni C. [b6]
Sent: Monday, May 11, 2020 12:19 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Question re: ACTIV and BayCare Health System (Florida)

Hi, Ashley,

I am writing at the suggestion of House Energy & Commerce Committee staff, who suggested you would be a great person with whom to start with a brief question outlined below.

I lead federal advocacy for [BayCare Health System](#), one of Florida's largest not-for-profit health systems, comprised of 15 hospitals and approximately 30,000 team members and physicians in West Central Florida (Tampa Bay area).

BayCare was glad to see last month's announcement regarding the creation of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership. As ACTIV continues its work, **is there someone on the team with whom we could speak about becoming involved as a large, not-for-profit hospital system in the State of Florida?**

We view this as a significant and very much needed development to help coordinate many different aspects of COVID-related research, and we would appreciate any insight you would have to connect with the group and its efforts.

APAR0000013508

Thanks so much,
Joni

Joni Higgins
Federal Government Relations Manager

BayCare Health System

b6

Confidential: This electronic message and all contents contain information from BayCare Health System which may be privileged, confidential or otherwise protected from disclosure. The information is intended to be for the addressee only. If you are not the addressee, any disclosure, copy, distribution or use of the contents of this message is prohibited. If you have received this electronic message in error, please notify the sender and destroy the original message and all copies.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 3:40:34 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Viewpoint on ACTIV
Attachments: JAMA ACTIV Clean_051120 edit1133AM.docx

Added today's publication in *Science* just released:

<https://science.sciencemag.org/content/early/2020/05/08/science.abc5312> to the references.

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, May 11, 2020 10:56 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Stoffels, Paul [JJCUS] [b6]
Subject: FW: Viewpoint on ACTIV

Looping in David regarding the question below.

From: Howard Bauchner [b6]
Sent: Monday, May 11, 2020 10:24 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Phil Fontanarosa [b6]; Stoffels, Paul [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Viewpoint on ACTIV

Francis/Paul

Thinking it would be helpful to name the folks from industry you have collaborated with at the end of the article – in additional information – suspect most readers will want to know who.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my chats with authors

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 9:03 AM
To: Howard Bauchner [b6]
Cc: Phil Fontanarosa [b6]; Stoffels, Paul [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Viewpoint on ACTIV

[Warning External Email]

Here you go. Many thanks for your very rapid response!!

APAR0000013511

Best, Francis

From: Howard Bauchner <[REDACTED] b6 [REDACTED]>
Sent: Sunday, May 10, 2020 1:47 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: Phil Fontanarosa <[REDACTED] b6 [REDACTED]>
Subject: Re: Viewpoint on ACTIV

Francis – attached are our edits –

Just return a clean copy and one with track changes to Phil and me.

Stay healthy.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my [chats with authors](#)

From: Francis Collins <[REDACTED] b6 [REDACTED]>
Date: Sunday, May 10, 2020 at 11:32 AM
To: Howard Bauchner <[REDACTED] b6 [REDACTED]>
Cc: "Stoffels, Paul" <[REDACTED] b6 [REDACTED]>, "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, Tony Fauci <[REDACTED] b6 [REDACTED]>, "Burklow, John (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, "Myles, Renate (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, "Parker, Ashley (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, "Kolberg, Rebecca (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, "Wolinetz, Carrie (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, "Wholley, David (FNIH) [T]" <[REDACTED] b6 [REDACTED]>, "Freire, Maria (FNIH) [T]" <[REDACTED] b6 [REDACTED]>
Subject: Viewpoint on ACTIV

[Warning External Email]

Dear Howard,

On behalf of Paul Stoffels and myself, please see attached a Viewpoint on the ACTIV public-private partnership that we would like to have considered for publication in JAMA. Because of the rapidly moving events surrounding the COVID-19 pandemic, your offer to review this quickly is much appreciated.

I will serve as corresponding author.

Many thanks, Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 2:44:17 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: Daily ACTIV Calls

Location: Dial-in: [b6] Passcode: [b6]

Start: 5/12/2020 12:15:00 PM

End: 5/12/2020 12:45:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 2:12:00 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV mtg with Exec Comm and WG co-chairs

Location: <https://fnih.zoom.us/j/91812121212> **b6**

Start: 5/13/2020 12:00:00 PM

End: 5/13/2020 1:00:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 2:00:24 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Viewpoint on ACTIV

Great – thanks.

Ashley

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >
Sent: Monday, May 11, 2020 9:59 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: Viewpoint on ACTIV

Thanks. I just alphabetized the members of the Exec Comm, and will send off.
FC

From: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Sent: Monday, May 11, 2020 9:26 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: Viewpoint on ACTIV

Deleted all of the language below the arrow – please see attached.

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >
Sent: Monday, May 11, 2020 9:24 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: Viewpoint on ACTIV

Got it. Can you also send the modified Figure?

From: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Sent: Monday, May 11, 2020 8:58 AM
To: Wholley, David (FNIH) [T] <[REDACTED] b6 >; Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >
Cc: Stoffels, Paul [JJCUS] <[REDACTED] b6 >
Subject: RE: Viewpoint on ACTIV

Hi Francis,

Please see the attached changes FNIH provided below in addition to the update on the number of identified networks by the clinical capacity WG – now “44”.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[REDACTED] b6 >
Sent: Monday, May 11, 2020 8:12 AM

To: Parker, Ashley (NIH/OD) [E] [b6] Collins, Francis (NIH/OD) [E] [b6]
Cc: Stoffels, Paul [JJCUS] [b6]
Subject: RE: Viewpoint on ACTIV

Hi Ashley:

Yes, please remove "vaccines" from the Clinical Tx working group description.

In the vaccines description, In the vaccines section we suggest that "This includes development of a harmonized master protocol for adaptive trials of **three or more** vaccines" to "This includes development of a harmonized master protocol for adaptive trials of **multiple** vaccines." I don't think we want to hem ourselves in by saying 3 or more.

I have a call in to Karen Tountas to confirm the number of sites (38) mentioned in the Clinical Trial Capacity WG so I can get you the latest updated number. Those are the only changes from us.
David

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Sunday, May 10, 2020 7:01 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Stoffels, Paul [JJCUS] [b6]
Subject: RE: Viewpoint on ACTIV

Hi Francis,

Looks fine but would only flag a few minor items to be confirmed. David – could your team confirm the items below?

- **The Clinical Therapeutics Working Group:** "To help achieve these goals, the group has established a steering committee with relevant expertise and objectivity to set criteria for evaluating and ranking potential candidate therapies and vaccines submitted by industry partners."
 - Is the agreement to have the clinical Tx WG evaluate and rank "vaccines"? Only confirming considering I understood the vaccine group would prioritize vaccine candidates using special criteria?
- **The Vaccines Working Group:** "This includes development of a harmonized master protocol for adaptive trials of three or more vaccines...."
 - There were discussions over the weekend regarding the master protocol for vaccines – uncertain of the final decision. Individual harmonized protocols?

Thank you for the opportunity to review.
Ashley

From: Stoffels, Paul [JJCUS] [b6]
Sent: Sunday, May 10, 2020 2:32 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Re: Viewpoint on ACTIV

All good. Please go ahead. Thanks for taking the lead. This is going to be a great partnership.

Have a bit of a relaxed sunday !

Paul

Verstuurd vanaf mijn iPad

Op 10 mei 2020 om 20:05 heeft Collins, Francis (NIH/OD) [E] [b6] het volgende geschreven:

Hi Paul,

I don't think I've ever seen a manuscript edited and returned in two hours! We must be working on something important.

The edits seem to be purely cosmetic. Please have a quick look, however, to be sure that there is no violence done to the meaning. I will do the same. I'm also cc'ing Ashley and David – and asking that they look closely at the description of the actions of the Working Groups, as well as the Figure, since ACTIV progress has been advancing almost by the hour.

If we can get this back to JAMA today, that would be great.

Thanks, Francis

From: Howard Bauchner [b6]
Sent: Sunday, May 10, 2020 1:47 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Phil Fontanarosa [b6]
Subject: Re: Viewpoint on ACTIV

Francis – attached are our edits –

Just return a clean copy and one with track changes to Phil and me.

Stay healthy.

HCB

Howard Bauchner, MD
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Please respect the confidentiality of this email

Listen to my [chats with authors](#)

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To: Howard Bauchner [b6]
Cc: "Stoffels, Paul" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], Tony Fauci [b6], "Burklow, John (NIH/OD) [E]" [b6]

APAR0000013546

[REDACTED] b6, "Myles, Renate (NIH/OD) [E]" [REDACTED] b6, "Parker, Ashley (NIH/OD) [E]" [REDACTED] b6, "Kolberg, Rebecca (NIH/OD) [E]" [REDACTED] b6, "Wolinetz, Carrie (NIH/OD) [E]" [REDACTED] b6, "Wholley, David (FNIH) [T]" [REDACTED] b6, "Freire, Maria (FNIH) [T]" [REDACTED] b6

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I will serve as corresponding author.

Many thanks, Francis

<JAMA ACTIV_050920 5-10-2020.docx>

<JAMA ACTIV Figure_050920.docx>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/11/2020 12:58:56 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: FW: Viewpoint on ACTIV
Attachments: JAMA ACTIV_050920 5-11-2020.docx

FYI

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, May 11, 2020 8:58 AM
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Cc: Stoffels, Paul [JJCUS] [b6]
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To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
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Editor in Chief of JAMA and the JAMA Network

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Cc: "Stoffels, Paul" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], Tony Fauci [b6], "Burklow, John (NIH/OD) [E]" [b6], "Myles, Renate (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Kolberg, Rebecca (NIH/OD) [E]" [b6], "Wolinetz, Carrie (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Freire, Maria (FNIH) [T]" [b6]
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[Warning External Email]

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<JAMA_ACTIV_050920 5-10-2020.docx>

<JAMA_ACTIV Figure_050920.docx>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/10/2020 11:51:21 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Keeping OCPL informed on ACTIV
Attachments: FNIH Covid 19 meeting April 03 2020 notes.docx; ACTIV_Leadership_Group_Meeting_Summary Notes April 22, 2020 final.docx; ACTIV Partnership Leadership Team Meeting 20200421 Final 2.pptx; 2020-05-06_ACTIV_Leadership_Group_Meeting_Summary FINAL.docx; ACTIV Partnership Leadership Team Meeting 20200506 FINAL.pptx

Good evening,

Thank you, Francis. Renate and John – please see the attached summary materials for ACTIV that we have to date. I shared the ACTIV leadership slides from the May 6th meeting on Wednesday – reattaching here.

- Summary of initial April 3rd meeting (if copies of the slides are needed we will have to ask FNIH) – 1st attachment
- Summary of April 22 leadership meeting and slides – 2nd and 3rd attachment
- Summary of May 6 leadership meeting and slides – 4th and last attachment

Please let me know if you need anything else.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Sunday, May 10, 2020 3:52 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Burklow, John (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Keeping OCPL informed on ACTIV

Hi Ashley,

In an effort to be sure that Renate and John are fully informed about everything that is happening with ACTIV, please pass along to them any minutes, slides, or other materials that might be relevant for their efforts to implement a communication plan.

Thanks, Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/10/2020 2:03:10 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Master Protocol Subgroup #15
Location: <https://fnih.zoom.us/j/91812345678> **b6**
Start: 5/11/2020 5:00:00 PM
End: 5/11/2020 6:30:00 PM

Recurrence: (none)

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/9/2020 6:11:59 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: Fwd: Tracking of ACTIV Emails -- Week Ending May 8, 2020
Attachments: image001.png; ATT00001.htm; ACTIV Emails_Queries rv 050820.xlsx; ATT00002.htm

Please see attached.

Thanks,
Ashley

Begin forwarded message:

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: May 8, 2020 at 8:14:44 PM EDT
To: "Collins, Francis (NIH/OD) [E]" [b6] >, "Tabak, Lawrence (NIH/OD) [E]" [b6]
[b6] "Wholley, David (FNIH) [T]" [b6]
Subject: Tracking of ACTIV Emails -- Week Ending May 8, 2020

Good evening,

Please see the attached spreadsheet with the additional email inquiries that were received for ACTIV this week.

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/9/2020 4:29:52 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: Re: ACTIV Meeting Today?

Thanks, Cheryl. I wrote Dr. Collins and others directly to ask about this – having a meeting today is still pending and Cliff Lane will provide an update to the group including David and Maria after a 2:30pm call.

Thanks so much,
Ashley

> On May 9, 2020, at 9:06 AM, Melencio, Cheryl (FNIH) [T] [b6] wrote:

>
> Good morning,

>
> I have not heard anything about this meeting.

>
> Cheryl

>
> Cheryl Melencio
> Administrative Manager, Research Partnerships
> Foundation for the National Institutes of Health

> [b6]
> fnih.org
> 11400 Rockville Pike Suite 600 North Bethesda, MD 20852

>
> Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

>
>
> -----Original Message-----

> From: Parker, Ashley (NIH/OD) [E] [b6]

> Sent: Saturday, May 9, 2020 8:01 AM

> To: Wood, Gretchen (NIH/OD) [E]

> Cc: Melencio, Cheryl (FNIH) [T] [b6]

> Subject: ACTIV Meeting Today?

>
> Good morning Gretchen,

>
> To ensure I plan my schedule accordingly – do you know if we are having a meeting with the vaccine WG co-chairs of ACTIV, FC, LAT, ASF, Cliff Lane, and FDA, David W? Cc'ing Cheryl as well in case she's coordinating these meetings.

>
> Thank you!
> Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/9/2020 1:39:24 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]
Subject: RE: Tracking of ACTIV Emails -- Week Ending May 8, 2020

Thanks, David. The NIH Executive Secretariat's office is sending a standard response to the inquiries we receive to ensure we acknowledge receipt of their emails but happy to follow up on these as needed.

The plan is for the portal to go live early next week!

Thank you,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 8, 2020 9:30 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];
Parker, Ashley (NIH/OD) [E] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; James, Stephanie (FNIH) [T] [b6]
Subject: FW: Tracking of ACTIV Emails -- Week Ending May 8, 2020

Ashley—lots of enthusiasm out there for sure. I am forwarding to my folks for triage, but of course not all of these are really ACTIV. We'll get back to you in a few days as to where these fit and where you might pursue actions or replies at least outside of ACTIV.

Thanks, David

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 8, 2020 8:15 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];
Wholley, David (FNIH) [T] [b6]
Subject: Tracking of ACTIV Emails -- Week Ending May 8, 2020

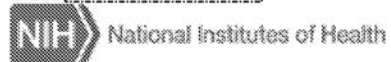
Good evening,

Please see the attached spreadsheet with the additional email inquiries that were received for ACTIV this week.

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health

Tel: b6



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/9/2020 1:27:09 AM
To: Jeff Schlesinger [b6]
CC: Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Cameron Durrant [b6]; Dale Chappell [b6]; Brian Reynolds [b6]; Herb Biggers [b6]; Victor Go [b6]; Kendal Strickland [b6]
BCC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: At the suggestion of Michael Kurilla - Presentation of Humanigen's Lenzilumab Therapy

Hi Jeff,


Michael shared your information and let me know you were interested in having Humanigen's therapeutic candidate Lenzilumab included for consideration with the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public private partnership.

As you can imagine, we are receiving a considerable number of inquiries from companies and I am managing these until we have our online portal ready. I've included your information in our database and will also forward to the co-chairs of our clinical therapeutics working group, and they may contact you.

In the meantime, please let me know if I can help with anything else.

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health

Tel: [b6]
 National Institutes of Health

From: Jeff Schlesinger [b6]
Sent: Friday, May 8, 2020 3:27 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Kurilla, Michael (NIH/NCATS) [E] [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Cameron Durrant [b6]; Dale Chappell [b6]; Brian Reynolds [b6]; Herb Biggers [b6]; Victor Go [b6]; Kendal Strickland [b6]
Subject: At the suggestion of Michael Kurilla - Presentation of Humanigen's Lenzilumab Therapy

Ashley,

Your name was given to me by Michael Kurilla after Humanigen gave him and Sam Bozzette a presentation on Lenzilumab, the Humanigen therapy to address COVID-19 through the reduction of the cytokine storm. They thought it would be extremely productive to schedule time with you, and also bring you through this therapy and see how NH can assist.

Are you available next Tuesday or Wednesday morning for a presentation?

We are all excited about addressing the COVID-19 and the feedback from Michael and Sam was extremely positive.

Please let me know what time works for you and I can schedule from our end.

Thank you Michael and Sam for the introduction.

Best regards,

Jeff Schlesinger
Managing Director
Chatham Capital Advisory, LLC

b6

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 4/30/2020 2:46:06 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

First I am seeing this. Francis, do you want me to reach out to Gary?

From: "Wholley, David (FNIH) [T]" [b6]
Date: Thursday, April 30, 2020 at 10:34 AM
To: Francis Collins [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

Francis and Larry:

Perhaps I am misunderstanding the intent of this announcement but it seems more than a little duplicative of what we are trying to do in ACTIV. My co-chairs certainly seem to think so. Can someone offer a perspective we can communicate on this please? Thanks, David

From: "Read, Sarah (NIH/NIAID) [E]" [b6]
Date: April 29, 2020 at 10:45:05 PM EDT
To: "Adam, Stacey (FNIH) [T]" [b6], Eric Hughes [b6]
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

This is interesting. I can't figure out the date of when this was published but it reads like a funding announcement for ACTIV...minus antivirals.

<https://www.nhlbi.nih.gov/sites/default/files/media/docs/COVID19-ROA-OTA-FINAL.pdf>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/8/2020 4:53:08 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: Accepted: ACTIV Clinical Trial Capacity Working Group - reporting meeting
Location: <https://fnih.zoom.us/j/91811571711> **b6**
Start: 5/26/2020 1:00:00 PM
End: 5/26/2020 2:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/8/2020 9:45:43 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: 2020-05-06_ACTIV_Leadership_Group_Meeting_Summary FINAL

Perfect – thank you!!

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 8, 2020 5:44 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: 2020-05-06_ACTIV_Leadership_Group_Meeting_Summary FINAL
Importance: High

Hi Ashley,

I know you asked for “action items” but there really was not a discrete short list of such that we could point to. Instead, we have plowed ahead and finished the notes for the entire meeting, attached. It includes the Q&A from the chatbox, which you might want to remove. As I recall this is what Francis used last time, and the Secretary was duly impressed. Hoping this will serve equally well this time.

David

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/8/2020 9:12:51 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Hopefully -- final attendee list for today's meeting

Thank you!!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, May 8, 2020 5:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Hopefully -- final attendee list for today's meeting

He thanked me for the reminder and said he is working on it with Deloitte

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 8, 2020 5:11 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: Hopefully -- final attendee list for today's meeting

Thanks!! I have not heard back.

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, May 8, 2020 4:00 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Hopefully -- final attendee list for today's meeting

I forwarded your message to David with high importance.

Attached is the latest list of additions for this week.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

APAR0000013611

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Parker, Ashley (NIH/OD) [E] b6
Sent: Friday, May 8, 2020 2:50 PM
To: Melencio, Cheryl (FNIH) [T] b6
Subject: FW: Hopefully -- final attendee list for today's meeting

Hi Cheryl,

Can you help flag this for David? He's probably all over it but just want to ensure he saw this – thanks!

Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, May 8, 2020 1:14 PM
To: Wholley, David (FNIH) [T] b6 Collins, Francis (NIH/OD) [E] b6
Subject: RE: Hopefully -- final attendee list for today's meeting

Hi David,

Touching base to see if the summary of action items from the ACTIV leadership meeting Wednesday are ready for sharing. We plan to include as an attachment for Francis to share with the Secretary early next week – we'd like to send these before COB today if possible.

Thank you very much,
Ashley

From: Wholley, David (FNIH) [T] b6
Sent: Wednesday, May 6, 2020 2:17 PM
To: Collins, Francis (NIH/OD) [E] b6
Cc: Parker, Ashley (NIH/OD) [E] b6
Subject: Re: Hopefully -- final attendee list for today's meeting

Yes action items by cob Thursday and notes by the weekend

Get [Outlook for iOS](#)

From: Collins, Francis (NIH/OD) [E] b6
Sent: Wednesday, May 6, 2020 2:15:38 PM
To: Wholley, David (FNIH) [T] b6
Cc: Parker, Ashley (NIH/OD) [E] b6
Subject: RE: Hopefully -- final attendee list for today's meeting

APAR0000013611

What can I commit to for timing of distribution of action items? 24 hours? And meeting summary by when? I see you have the Rose Li science writer signed up, which is great.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:56 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Hopefully -- final attendee list for today's meeting

The list so far. Cheryl has sent out email to those who have not responded to get an rsvp.

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:21 PM
To: Wholley, David (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: Hopefully -- final attendee list for today's meeting

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/8/2020 2:17:30 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: RE: FOR REVIEW: ES - WF 390743 - Writer seeks information on the ACTIV partnership. (Syneos)

OK, thanks! I will let ES know they can respond: we are coordinating with other agencies and the White House.

Thanks again!

From: Wolinetz, Carrie (NIH/OD) [E] [b6]
Sent: Friday, May 8, 2020 10:06 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: FOR REVIEW: ES - WF 390743 - Writer seeks information on the ACTIV partnership. (Syneos)

I think we just say that we are coordinating with other agencies and the White House.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 8, 2020 9:46 AM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]
Subject: RE: FOR REVIEW: ES - WF 390743 - Writer seeks information on the ACTIV partnership. (Syneos)

Suggestions? I did not want to talk about the WH effort.

From: Wolinetz, Carrie (NIH/OD) [E] [b6]
Sent: Friday, May 8, 2020 9:46 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: FOR REVIEW: ES - WF 390743 - Writer seeks information on the ACTIV partnership. (Syneos)

It doesn't actually answer the question.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, May 8, 2020 9:41 AM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]
Subject: FOR REVIEW: ES - WF 390743 - Writer seeks information on the ACTIV partnership. (Syneos)

Hi Carrie,

Based on the writers question to FNIH, I think we may need to share more than our standard response ES shares. Please see draft below.

Dear Dr. Renaud Seigneuric,

We received your request from the Foundation for the National Institutes of Health (FNIH) regarding your interest in understanding the connection between the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) and additional federal activities to speed treatment options for COVID-19. The National Institutes of Health (NIH) and FNIH coordinated public private partnership ACTIV, brings together multiple federal agencies, 18 industry partners, and

academia to accelerate therapeutics and vaccines for COVID-19. Please see the [ACTIV](#) press release for additional information on the four fast track working group activities which focus on preclinical therapeutics, clinical therapeutics, clinical capacity, and vaccines for COVID-19.

NIH also launched the Rapid Acceleration of Diagnostics (RADx), a Shark Tank-like initiative to accelerate diagnostics for testing of COVID-19. This project will speed innovation, development and commercialization of COVID-19 diagnostic technologies, additional information can be found in the [NIH RADx press release](#).

As you are aware, this is an unprecedented time and federal health agencies are working to speed therapeutics, vaccines, diagnostics, and technologies to tackle COVID-19.

Best Regards,
NIH Executive Secretariat

From: EDRMS NO_REPLY@mail.nih.gov <EDRMS_NO_REPLY@mail.nih.gov>
Sent: Friday, May 8, 2020 7:15 AM
To: Parker, Ashley (NIH/OD) [E] [b6] EDRMS_NO_REPLY@mail.nih.gov
Subject: ES - WF 390743 - FYI (Liaison)

Work Folder Information

Work Folder: WF 390743

Process: FYI

Program Analyst: Whitfield, Michelle D. (NIH/OD) [E]

Due Date:

WF Subject: Writer seeks information on the ACTIV partnership. (Syneos)

IC: od_cos

From: Jaeger, Cheryl L.

To: Wolinetz, Carrie

Remarks: FYI to CoS, OSP, and NIAID. ES will send an acknowledgement email.

From: "Meltzer, Abbey (FNIH) [T]" [b6]
Date: May 5, 2020 at 9:24:22 PM EDT
To: "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: ACTIV & Warp Speed

Dear Ashley,

Please see below for another inquiry that we received.

Best,
Abbey

From: Renaud SEIGNEURIC [b6]
Sent: Monday, May 4, 2020 1:42 PM
To: Meltzer, Abbey (FNIH) [T] [b6]
Subject: ACTIV & Warp Speed

Dear Abbey Meltzer,

I hope my email finds you well.

I learned about the ACTIV initiative and find it very stimulating and full of hope, thank you. I was wondering how ACTIV was actually connected to the Operation Warp Speed.

Could you let me know please?
Thank you in advance for your reply,
Best regards
Renaud SEIGNEURIC

Renaud SEIGNEURIC, Dr., PhD | Scientific Attaché, Physical Sciences and Nanotechnology, Biomedical Sciences, Translational Research and Innovation

Office for Science and Technology | General Consulate of France in Houston

777 Post Oak Blvd, Suite 600 – Houston, TX 77056 – USA

b6

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Office for Science and Technology of the French Embassy in the US | [CONNECT](#)



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/8/2020 11:33:42 AM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: ES - WF 390739 - Potential participation in ACTIV
Attachments: FW: Potential participation in ACTIV

FYI

From: EDRMS_NO_REPLY@mail.nih.gov <EDRMS_NO_REPLY@mail.nih.gov>
Sent: Friday, May 8, 2020 7:26 AM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] EDRMS_NO_REPLY@mail.nih.gov
Subject: ES - WF 390739 - FYI (Liaison)

Work Folder Information

Work Folder: WF 390739

Process: FYI

Program Analyst: Whitfield, Michelle D. (NIH/OD) [E]

Due Date:

WF Subject: PTC Therapeutics seeks information on the ACTIV partnership.

IC: od_cos

From: Pykett, Mark

To: Freire, Maria

Remarks: FYI to CoS, OSP, and NIAID.

From: Freire, Maria (FNIH) [T] [REDACTED]
Sent: Wednesday, May 6, 2020 1:38 PM
To: Parker, Ashley (NIH/OD) [E] [REDACTED]
Cc: Adam, Stacey (FNIH) [T] [REDACTED]; Santos, Michael (FNIH) [T] [REDACTED]
Subject: Fwd: Potential participation in ACTIV

Ashley, for Exec Sec.

Stacey, Mike - FYI and use as appropriate.

Best to all, M.

Begin forwarded message:

From: "Pykett, Mark" [REDACTED]
Date: May 6, 2020 at 12:33:51 PM GMT-5
To: "Freire, Maria (FNIH) [T]" [REDACTED]
Subject: Potential participation in ACTIV

Dear Dr. Freire,

I hope my note finds you all safe and well. My name is Mark Pykett and I am the Chief Scientific Officer of PTC Therapeutics, a biopharmaceutical company located in South Plainfield, NJ. The company is engaged in discovery,

APAR0000013620

development and commercialization of novel therapeutics for rare and neglected diseases with high unmet medical need. PTC has a global footprint of over 900 people and currently has four marketed products.

We have learned with great interest about the planned ACTIV public-private partnership to coordinate and accelerate the development of COVID-19 vaccines and treatment options. PTC has an orally-bioavailable clinical stage compound, PTC299, with a unique, dual-mechanism of action that is highly differentiated from other drugs and we believe has high potential in treating COVID-19 patients. PTC299 is well positioned for human clinical testing as a COVID-19 treatment based on the following reasons:

b4

We believe that PTC299's profile and PTC's expertise and commitment to helping find treatments for COVID-19 align perfectly with the goals of ACTIV. PTC Therapeutics is interested in learning more about the opportunity and explore ways to become a member of ACTIV partnership.

We would be grateful if you could share with us entry criteria, eligibility requirements for the program, and your view of the next steps for ACTIV. If you need any additional information, I would be happy to provide it.

With kind regards,

Mark

Mark Pykett, VMD, PhD
Chief Scientific Officer

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 6:16:01 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Potential participation in ACTIV

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:38 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]
Subject: Fwd: Potential participation in ACTIV

Ashley, for Exec Sec.

Stacey, Mike - FYI and use as appropriate.

Best to all, M.

Begin forwarded message:

From: "Pykett, Mark" [b6]
Date: May 6, 2020 at 12:33:51 PM GMT-5
To: "Freire, Maria (FNIH) [T]" [b6]
Subject: Potential participation in ACTIV

Dear Dr. Freire,

I hope my note finds you all safe and well. My name is Mark Pykett and I am the Chief Scientific Officer of PTC Therapeutics, a biopharmaceutical company located in South Plainfield, NJ. The company is engaged in discovery, development and commercialization of novel therapeutics for rare and neglected diseases with high unmet medical need. PTC has a global footprint of over 900 people and currently has four marketed products.

We have learned with great interest about the planned ACTIV public-private partnership to coordinate and accelerate the development of COVID-19 vaccines and treatment options. PTC has an orally-bioavailable clinical stage compound, PTC299, with a unique, dual-mechanism of action that is highly differentiated from other drugs and we believe has high potential in treating COVID-19 patients. PTC299 is well positioned for human clinical testing as a COVID-19 treatment based on the following reasons:

b4

b4

We believe that PTC299's profile and PTC's expertise and commitment to helping find treatments for COVID-19 align perfectly with the goals of ACTIV. PTC Therapeutics is interested in learning more about the opportunity and explore ways to become a member of ACTIV partnership.

We would be grateful if you could share with us entry criteria, eligibility requirements for the program, and your view of the next steps for ACTIV. If you need any additional information, I would be happy to provide it.

With kind regards,

Mark

Mark Pykett, VMD, PhD
Chief Scientific Officer

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/8/2020 11:23:27 AM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: ES - WF 390744 - Ester Krofah (Milken Institute) forwards information on Biomarck Pharmaceuticals project
Attachments: 1a Biomarck_Milken presentation_March 2020.pdf; 1b Biomarck ARDS GOVERNMENT_April 2020 vF.PDF; FW: Biomarck -BIO-11006 ARDS compound for COVID 19

FYI

From: EDRMS_NO_REPLY@mail.nih.gov <EDRMS_NO_REPLY@mail.nih.gov>
Sent: Friday, May 8, 2020 7:10 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; EDRMS_NO_REPLY@mail.nih.gov
Subject: ES - WF 390744 - FYI (Liaison)

Work Folder Information

Work Folder: WF 390744

Process: FYI

Program Analyst: Whitfield, Michelle D. (NIH/OD) [E]

Due Date:

WF Subject: Ester Krofah (Milken Institute) forwards information on Biomarck Pharmaceuticals project for consideration for ACTIV partnership.

IC: od_cos

From: Krofah, Esther

To: Wholley, David

Remarks: FYI to CoS, OSP, and NIAID.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 9:31 AM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Lane, Cliff (NIH/NIAID) [E] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Biomarck -BIO-11006 ARDS compound for COVID 19

Hi, Stacey

I had a half-hour productive conversation with Esther Krofah and Brenda Honeycutt from Faster Cures yesterday to update them on ACTIV and hear what they are doing in the COVID field. She cited 1) their tracker for COVID therapeutics and vaccines (which I thanked her for making available, as we have been using it in our Tx prioritization efforts) 2) some policy work they are doing with NIH, primarily NCATS, and their business council around the COVID response, which she says will be posted later this week on their website 3) a post-COVID "early warning" surveillance system for future pandemics they are looking to develop 4) an analysis of promising compounds that could be used in platform trials. The Biomarck drug below has apparently risen to the top of the heap as she put it. They had a meeting with BARDA last week that Esther claimed showed good safety and efficacy data out of a Phase II. I am simply sending this to you and to Ashley so it gets on our respective "lists" of things to consider if it is not already on there.

Thanks, David

From: Esther Krofah [b6]
Sent: Monday, May 4, 2020 12:13 PM

To: Wholley, David (FNIH) [T] { b6 }

Subject: Biomarck -BIO-11006 ARDS compound for COVID 19

Hi David,

It was great speaking with you and thanks for all you're doing. As mentioned, Biomarck Pharmaceuticals based in Research Triangle Park, N.C. has an asset BIO-11006 that has the potential first to market treatment option in ARDS. They have received Orphan Drug designation from the FDA and expect to obtain priority review in ARDS. Their Phase 2 data demonstrated a mortality reduction of >40% in ARDS patients. Announcement of their results is here: [click here](#). The compound has a well-established clinical safety profile with over 200 patients exposed and there is strong interest in accelerating into clinical trial for COVID-19. Please see the attached documents. They had a meeting with BARDA last week that went well and have submitted their Phase 2 data to FDA. Application number: IND070296. This would be a worthwhile company to speak with and consider for acceleration in the ACTIV therapeutic accelerator. I am happy to make an introduction or see contact information below to the Chairman of the company.

Rajin Ahuja | Executive Chairman of the Board

Biomarck Pharmaceuticals - 2530 Meridian Parkway Suite 300, Durham, NC 27713

C: b6 biomarck.com

All the best,
Esther



Esther Krofah
Executive Director
FasterCures



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 2:27:39 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Biomarck -BIO-11006 ARDS compound for COVID 19
Attachments: Biomarck ARDS GOVERNMENT_April 2020 vF.PDF; Biomarck_Milken presentation_March 2020.pdf

FYI only.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 9:31 AM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Biomarck -BIO-11006 ARDS compound for COVID 19

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Thanks, David

From: Esther Krofah [b6]
Sent: Monday, May 4, 2020 12:13 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: Biomarck -BIO-11006 ARDS compound for COVID 19

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Rajin Ahuja | Executive Chairman of the Board
Biomarck Pharmaceuticals - 2530 Meridian Parkway Suite 300, Durham, NC 27713
C: [b6] biomarck.com

APAR0000013629

All the best,
Esther



Esther Krofah
Executive Director
FasterCures

b6

milkeninstitute.org



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/7/2020 9:09:05 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]

Subject: Accepted: ACTIV TX-Clinical Working Group #6

Location: <https://fnih.zoom.us/j/91812121212> **b6**

Start: 5/14/2020 6:00:00 PM

End: 5/14/2020 7:00:00 PM

Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/7/2020 9:09:00 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Master Protocol Subgroup Meeting #17
Location: <https://fnih.zoom.us/j/91812121212> **b6**
Start: 5/15/2020 5:00:00 PM
End: 5/15/2020 6:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/7/2020 9:08:45 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Agent Prioritization Subgroup #10
Location: https://fnih.zoom.us/j/b6
Start: 5/14/2020 5:00:00 PM
End: 5/14/2020 6:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/7/2020 9:08:16 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Master Protocol Subgroup Meeting #16
Location: <https://fnih.zoom.us/j/91812121212> **b6**
Start: 5/13/2020 5:00:00 PM
End: 5/13/2020 6:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/7/2020 9:08:13 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Agent Prioritization Subgroup #9
Location: https://fnih.zoom.us/j/b6
Start: 5/12/2020 5:00:00 PM
End: 5/12/2020 6:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/7/2020 9:08:11 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Master Protocol Subgroup #15
Location: <https://fnih.zoom.us> b6
Start: 5/11/2020 5:00:00 PM
End: 5/11/2020 6:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/7/2020 3:38:06 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ACTIV Initiative

The specific information can be found under the clinical capacity tab of the spreadsheet shared – please see snapshot below.

A	B	C	D	E
Monica R. Shah, MD, FACC Vice President and Head, Cell and Gene Therapy Center of Excellence Therapeutic Strategy and Science Design and Delivery Innovations Art	Monica.Shah@nih.gov	I read about the NIH public-private partnership to speed COVID-19 vaccine and treatment options. I saw that the list of industry partners had leading pharma, but that there were no CROs. IQVIA has a strong commitment to patient-centeredness and resources to execute patient-centered, data-driven trials. We have comprehensive virtual trial capabilities as well direct to patient solutions that might be very helpful to this effort.	Thursday, April 23, 2020 at 10:56 AM	Sent to Mike Leaver; Work Folder: 390388
Arthur S. Levine, M.D. Senior Vice Chancellor for the Health Sciences John and Gertrude Petersen Dean, School of Medicine Professor of Medicine, Molecular Genetics and Neurobiology University of Pittsburgh Anantha Anamika Shukla, M.D., Ph.D. Senior Vice Chancellor for the Health Sciences Designee and John and Gertrude Petersen Dean, School of Medicine Designee, University of Pittsburgh until May 31, 2020; Distinguished Professor and Associate Vice President of Research and Clinical	alevine@pitt.edu	We read with excitement your announcement regarding the desire to lead, via the PNM, an international government-industry-academic partnership for the rapid evaluation of potential therapies for COVID-19. We would like to draw your attention to the existing adaptive platform trial, REMAP-CAP (www.remapcap.org), and its sub-platform specifically targeting COVID-19 (REMAP-COVIG). This platform trial uses a modular design, allowing the simultaneous evaluation of multiple therapies within different domains (such as anti-virals and host immune modulators). It already has funding from multiple international governments, including Canada, the UK, the EU, Australia and New Zealand. It is run by a large collaborative of academic clinical trial networks and universities, with coordinating centers in Pittsburgh, Toronto, London, Utrecht, and Melbourne. The Pittsburgh coordinating center is led by Professor Derek Angus, a long-standing NIH investigator who has conducted multiple NIH-funded studies. In addition, the underlying statistical design was built by Berry Consultants, who serve as NCI's innovative Clinical Trials Resource (ICTR). Angus and Berry Consultants led the initial design of REMAP-CAP, which was funded via the EU's FP7 mechanism. The trial has been endorsed by the UK NHS as one of 3 platform trials to be deployed in every hospital in Britain; it is already live in 13 countries; and it represents a perfect vehicle, in our estimation, for some of the goals and objectives outlined in your announcement.	Friday, April 24, 2020 11:33 AM	FC email: VFP390391
<div> <div>Preclinical Tx Potential</div> <div>Clinical Tx Potential</div> <div>Clinical Capacity Potential</div> <div>Vaccine Potential</div> <div>Other_Not ACTIV</div> </div>				

From: Freire, Maria (FNIH) [T] [b6]
Sent: Thursday, May 7, 2020 11:33 AM
To: Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: ACTIV Initiative

FYI - she got on the NIH list on April 23. It would be good to point to that so she gets the sense that we are all connected.

M.

From: "Tountas, Karen (FNIH) [T]" [b6]
Date: Thursday, May 7, 2020 at 10:30:19 AM
To: "Wholley, David (FNIH) [T]" [b6]
Cc: "Freire, Maria (FNIH) [T]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: RE: ACTIV Initiative

Thanks David, please steer her my way.
Karen

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 7, 2020 11:27 AM
To: Tountas, Karen (FNIH) [T] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: ACTIV Initiative

Karen, I would imagine IQVIA is on the list of CROs being contacted by the Clinical Trial Capacity WG, yes? Should I write Monica a note and steer her your way?

From: Freire, Maria (FNIH) [T] [b6]
Sent: Thursday, May 7, 2020 9:18 AM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Fwd: ACTIV Initiative

Ashley, for your list.

David, any special response required?

Begin forwarded message:

From: "Shah, Monica" [b6]
Date: May 7, 2020 at 8:13:11 AM GMT-5
To: "Freire, Maria (FNIH) [T]" [b6]
Subject: ACTIV Initiative

Dear Dr. Freire,

I hope that you are well. My name is Monica Shah and I am the Head of the Cell and Gene Therapy Center of Excellence, which is part of the Division of Design and Delivery Innovation at IQVIA. Prior to joining IQVIA I was at the NIH for almost a decade and held leadership positions at NHLBI and NCATS. My passion is optimizing the clinical research enterprise and accelerating the development of cures through innovation and public-private collaboration.

To that end, IQVIA would be very interested in joining the ACTIV Consortium to accelerate the development of new treatments and vaccines for COVID-19. As you may know, IQVIA (formerly QuintilesIMS) is the world's largest contract research organization (CRO), and has access to unparalleled data assets and analytics and vast array of patient-centered and data-driven resources to optimize the execution of clinical trials.

I was reviewing the impressive list of industry collaborators that are currently participating in the consortium, but saw that there were no CROs included. We think we could bring a complementary perspective and unique set of skills and resources to help the ACTIV Consortium achieve its goals. If possible, we would be delighted to further explore this with you with an introductory conversation.

Thank you and best wishes for success in this endeavor.

Sincerely,
Monica

Monica R. Shah, MD, FACC
Vice President and Head, Cell and Gene Therapy Center of Excellence
Therapeutic Strategy and Science
Design and Delivery Innovations



[Learn more](#) about IQVIA

Washington, DC
USA

O: b6

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/7/2020 3:11:07 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ACTIV Initiative

Hi Maria,

Monica Shah contacted our office on 4/23 – the request was captured in our spreadsheet and has been shared with the working groups.

Thank you,
Ashley

From: Freire, Maria (FNIH) [T] [b6]
Sent: Thursday, May 7, 2020 9:18 AM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Fwd: ACTIV Initiative

Ashley, for your list.

David, any special response required?

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Thank you and best wishes for success in this endeavor.

Sincerely,
Monica

Monica R. Shah, MD, FACC
Vice President and Head, Cell and Gene Therapy Center of Excellence
Therapeutic Strategy and Science
Design and Delivery Innovations



[Learn more](#) about IQVIA

Washington, DC
USA

O: b6

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 9:48:24 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: RE: Biomarck -BIO-11006 ARDS compound for COVID 19

Thank you!!

From: Wooldridge, Shannon (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 5:48 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Biomarck -BIO-11006 ARDS compound for COVID 19

That makes sense. Thank you for the clarification – I'll make a note in the WF.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 5:47 PM
To: Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: RE: Biomarck -BIO-11006 ARDS compound for COVID 19

Yes it should be uploaded to ensure others see this. I'm thinking my FYI only was intended to mean it does not require the standard response from ES given FNIH has responded via conversation with the group.

From: Wooldridge, Shannon (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 5:39 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Biomarck -BIO-11006 ARDS compound for COVID 19

Hi Ashley,

Do you want this one uploaded to DDRMS for assignment as well? Or just for ES records? Wasn't sure because of your "FYI only" notation. Thanks!!

Shannon

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 10:28 AM
To: Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: FW: Biomarck -BIO-11006 ARDS compound for COVID 19

FYI only.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 9:31 AM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Biomarck -BIO-11006 ARDS compound for COVID 19

Hi, Stacey

I had a half-hour productive conversation with Esther Krofah and Brenda Honeycutt from Faster Cures yesterday to update them on ACTIV and hear what they are doing in the COVID field. She cited 1) their tracker for COVID therapeutics and vaccines (which I thanked her for making available, as we have been using it in our Tx prioritization efforts) 2) some policy work they are doing with NIH, primarily NCATS, and their business council around the COVID response, which she says will be posted later this week on their website 3) a post-COVID "early warning" surveillance system for future pandemics they are looking to develop 4) an analysis of promising compounds that could be used in platform trials. The Biomarck drug below has apparently risen to the top of the heap as she put it. They had a meeting with BARDA last week that Esther claimed showed good safety and efficacy data out of a Phase II. I am simply sending this to you and to Ashley so it gets on our respective "lists" of things to consider if it is not already on there.

Thanks, David

From: Esther Krofah [b6]
Sent: Monday, May 4, 2020 12:13 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: Biomarck -BIO-11006 ARDS compound for COVID 19

Hi David,

It was great speaking with you and thanks for all you're doing. As mentioned, [Biomarck Pharmaceuticals](#) based in Research Triangle Park, N.C. has an asset BIO-11006 that has the potential first to market treatment option in ARDS. They have received Orphan Drug designation from the FDA and expect to obtain priority review in ARDS. Their Phase 2 data demonstrated a mortality reduction of >40% in ARDS patients. Announcement of their results is here: [click here](#). The compound has a well-established clinical safety profile with over 200 patients exposed and there is strong interest in accelerating into clinical trial for COVID-19. Please see the attached documents. They had a meeting with BARDA last week that went well and have submitted their Phase 2 data to FDA. Application number: IND070296. This would be a worthwhile company to speak with and consider for acceleration in the ACTIV therapeutic accelerator. I am happy to make an introduction or see contact information below to the Chairman of the company.

Rajin Ahuja | Executive Chairman of the Board
Biomarck Pharmaceuticals - 2530 Meridian Parkway Suite 300, Durham, NC 27713
C: [b6] | biomarck.com

All the best,
Esther



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 9:25:57 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership
Attachments: Syneos Health Company Fact Sheet_2020.pdf

From: Cheryl L. Jaeger <[REDACTED] b6>
Sent: Wednesday, May 6, 2020 3:52 PM
To: Wolinetz, Carrie (NIH/OD) [E] <[REDACTED] b6>
Subject: Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership

Carrie---

I hope this message finds you well. I'm hopeful you can recommend the best point of contact at FNIH for us to connect Syneos with the team that is working on Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership? I linked the specific program of interest below. Also please find attached a brief overview of the work Syneos has underway to improve clinical trials.

https://fnih.org/news/press-releases/nih-launches-partnership-to-speed-covid19-vaccines-treatments?utm_source=FNIH+Newsletter&utm_campaign=df5e0a10b6-EMAIL_CAMPAIGN_2020_04_17_11_42&utm_medium=email&utm_term=0_d72662a3eb-df5e0a10b6-40219447#utm_source=email&utm_medium=button&utm_campaign=activ_partnership

Thanks in advance for your help and consideration!

Sincerely,
Cheryl Jaeger

Cheryl Jaeger

Principal

Williams & Jensen, PLLC

[REDACTED] b6 cell

NEW ADDRESS:

1201 Pennsylvania Avenue, NW

Suite 800

Washington, DC 20004

APAR0000013676

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 8:04:40 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: RE: Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership

Yes, they go into this spreadsheet I've been developing for several weeks now which is then forwarded to the ACTIV WGs – I will it to ES who will send them a standard response.

The portal for these inquiries should be ready before early next week!

From: Wolinetz, Carrie (NIH/OD) [E] [REDACTED]
Sent: Wednesday, May 6, 2020 3:56 PM
To: Parker, Ashley (NIH/OD) [E] [REDACTED]
Subject: FW: Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership

If I send these to you, do they actually go somewhere. Or am I just screaming into the void? 😞

From: Cheryl L. Jaeger [REDACTED]
Sent: Wednesday, May 6, 2020 3:52 PM
To: Wolinetz, Carrie (NIH/OD) [E] [REDACTED]
Subject: Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership

Carrie---

I hope this message finds you well. I'm hopeful you can recommend the best point of contact at FNIH for us to connect Syneos with the team that is working on Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership? I linked the specific program of interest below. Also please find attached a brief overview of the work Syneos has underway to improve clinical trials.

https://fnih.org/news/press-releases/nih-launches-partnership-to-speed-covid19-vaccines-treatments?utm_source=FNIH+Newsletter&utm_campaign=df5e0a10b6-EMAIL_CAMPAIGN_2020_04_17_11_42&utm_medium=email&utm_term=0_d72662a3eb-df5e0a10b6-40219447#utm_source=email&utm_medium=button&utm_campaign=activ_partnership

Thanks in advance for your help and consideration!

Sincerely,
Cheryl Jaeger

Cheryl Jaeger

Principal

Williams & Jensen, PLLC

APAR0000013686

NEW ADDRESS:

1201 Pennsylvania Avenue, NW

Suite 800

Washington, DC 20004

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 7:42:45 PM
To: Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb4626dabbb45aa8b8e5d21169344e6-dennyjc]
Subject: RE: Hopefully -- final attendee list for today's meeting

Perfect!

From: Denny, Joshua (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 3:42 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Hopefully -- final attendee list for today's meeting

Thanks, Ashley. I'm on.

On May 6, 2020, at 2:55 PM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Hi Joshua,

Yes, you are on the list.

Thank you,
Ashley

From: Denny, Joshua (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 2:49 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Hopefully -- final attendee list for today's meeting
Importance: High

Ashley, you have me on there, right? I'm going to join since she can't. I have it on my calendar but realize I might not be on the list.

On May 6, 2020, at 2:23 PM, Denny, Joshua (NIH/OD) [E] [b6] wrote:

Larry,
Completely understand. I will let her know.
Thanks,
Josh

On May 6, 2020, at 2:16 PM, Tabak, Lawrence (NIH/OD) [E] [b6] wrote:

Josh

I am sorry but Sheri Schully cannot join the call with with ACTIV FNIH group today as it is for ICDs only. We are adding you because of the potential role of all of us.
Please let her know.
Larry

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, May 6, 2020 at 2:09 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: RE: Hopefully -- final attendee list for today's meeting

I saw that – she's the Deputy Chief Medical and Scientific Officer for All of Us.

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 2:04 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Hopefully -- final attendee list for today's meeting

Who is

Schully, Sheri (NIH/OD)

Required Attendee

Accepted

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, May 6, 2020 at 1:59 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: FW: Hopefully -- final attendee list for today's meeting

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:56 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Hopefully -- final attendee list for today's meeting

The list so far. Cheryl has sent out email to those who have not responded to get an rsvp.

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:21 PM
To: Wholley, David (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: Hopefully -- final attendee list for today's meeting

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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<image001.png>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 5:44:51 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Yes, they are different. IC Directors and the heads of the 27 NIH institutes and centers i.e. Fauci (NIAID); Chris Austin (NCATS); Gary Gibbons (NHLBI) etc.

Program Directors lead specific initiatives/programs that fall under an IC – in this case Matt Gilman falls under the Office of the Director (OD) – I think Larry has Tara representing OD unless this is an exception.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:37 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Forgive my ignorance. Is a Program Director an IC Director? Per Larry's distinction this morning.

From: Jenkins, Ashley (NIH/OD) [C] [b6]
Sent: Wednesday, May 6, 2020 1:35 PM
To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Luetkemeier, Erin (NIH/OD) [E] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Good Afternoon,

I apologize for the late request, May I have the call in details on behalf of Dr. Matthew Gillman?
I'd like to add the details to his meeting invite.

Thank you in advance,

Ashley Jenkins (C)
Operations Coordinator, Contractor
Executive Assistant, Dr. Matthew Gillman
Enviromental Influences on Child Health Outcomes (ECHO)
Office of the Director, National Institute of Health
Phone: [b6]
[b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 11:18 AM
To: ICDDIR-L@LIST.NIH.GOV
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Dear Colleagues,

As you may be aware, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership has been moving forward rapidly to address the global pandemic. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines.

Although some ICs have representatives participating in the working groups, we recognize there is a need to keep everyone looped in to the various activities and progress of the partnership, particularly in view of all of the concurrent IC projects about COVID-19. The ACTIV working groups will be delivering their second report to the **ACTIV Leadership Group on Wednesday, May 6, from 3:30-5:00pm**. I am writing to invite the ICDs to listen-in on this meeting. There will be a lot to cover during the meeting and the members of the Leadership Group will be asking the questions. But to give a chance for us NIHers to discuss what has been presented, I am scheduling a separate ICD call for 5:05-5:30pm, immediately following the ACTIV leadership meeting.

If you are available to take part, please send your responses to David Wholley and Cheryl Melencio of FNIH (cc'd here) by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and the ICD follow-up call.

Best regards,
Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 7:20:20 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: FW: Updated lists
Attachments: ACTIV May 6 Leadership Team Attendance.xlsx

I think this is the final list for today.

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 3:17 PM
To: Wholley, David (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Updated lists

David

After the ping, I received confirmations from:
Colvis. Erbeling, Johnson, Meeker, Read, Tsai

They will attend.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 6:51:11 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Thanks!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 2:30 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6
Importance: High

Dr. Joshua Gordon, NIMH cannot attend 3:30 but Tracy just told me he is now able to join 5:05 p.m. I sent him the invite for 5:05

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Holt, Tracy (NIH/NIMH) [E] [b6]
Sent: Wednesday, May 6, 2020 2:26 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6
Importance: High

Hi Cheryl,

Can Dr. Gordon join the 5:05pm call this evening? Unfortunately he is not able to join the 3:30pm call but his schedule is now open at 5:05pm.

Thank you,
Tracy

Tracy Holt
National Institute of Mental Health
Office of the Director
31 Center Drive
Suite 4A52, MSC 2116

APAR0000013699

Bethesda, MD 20892

b6

(direct line)
(main office)

b6

From: Collins, Francis (NIH/OD) [E] b6

Sent: Monday, May 4, 2020 11:18 AM

To: ICDDIR-L@LIST.NIH.GOV

Cc: Parker, Ashley (NIH/OD) [E] b6 Wholley, David (FNIH) [T] b6; Melencio, Cheryl (FNIH) [T] b6

Subject: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Dear Colleagues,

As you may be aware, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership has been moving forward rapidly to address the global pandemic. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines.

Although some ICs have representatives participating in the working groups, we recognize there is a need to keep everyone looped in to the various activities and progress of the partnership, particularly in view of all of the concurrent IC projects about COVID-19. The ACTIV working groups will be delivering their second report to the **ACTIV Leadership Group on Wednesday, May 6, from 3:30-5:00pm**. I am writing to invite the ICDs to listen-in on this meeting. There will be a lot to cover during the meeting and the members of the Leadership Group will be asking the questions. But to give a chance for us NIHers to discuss what has been presented, I am scheduling a separate ICD call for 5:05-5:30pm, immediately following the ACTIV leadership meeting.

If you are available to take part, please send your responses to David Wholley and Cheryl Melencio of FNIH (cc'd here) by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and the ICD follow-up call.

Best regards,
Francis

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 6:15:50 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: Potential participation in ACTIV

Thank you, Maria.

Ashley

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:38 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]
Subject: Fwd: Potential participation in ACTIV

Ashley, for Exec Sec.

Stacey, Mike - FYI and use as appropriate.

Best to all, M.

Begin forwarded message:

From: "Pykett, Mark" [b6]
Date: May 6, 2020 at 12:33:51 PM GMT-5
To: "Freire, Maria (FNIH) [T]" [b6]
Subject: Potential participation in ACTIV

Dear Dr. Freire,

I hope my note finds you all safe and well. My name is Mark Pykett and I am the Chief Scientific Officer of PTC Therapeutics, a biopharmaceutical company located in South Plainfield, NJ. The company is engaged in discovery, development and commercialization of novel therapeutics for rare and neglected diseases with high unmet medical need. PTC has a global footprint of over 900 people and currently has four marketed products.

We have learned with great interest about the planned ACTIV public-private partnership to coordinate and accelerate the development of COVID-19 vaccines and treatment options. PTC has an orally-bioavailable clinical stage compound, PTC299, with a unique, dual-mechanism of action that is highly differentiated from other drugs and we believe has high potential in treating COVID-19 patients. PTC299 is well positioned for human clinical testing as a COVID-19 treatment based on the following reasons:

[b4]

b4

We believe that PTC299's profile and PTC's expertise and commitment to helping find treatments for COVID-19 align perfectly with the goals of ACTIV. PTC Therapeutics is interested in learning more about the opportunity and explore ways to become a member of ACTIV partnership.

We would be grateful if you could share with us entry criteria, eligibility requirements for the program, and your view of the next steps for ACTIV. If you need any additional information, I would be happy to provide it.

With kind regards,

Mark

Mark Pykett, VMD, PhD
Chief Scientific Officer

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APAR0000013702

to notify us of the error and delete the original message and any attachments. The views or opinions presented in this message are solely those of the author and do not necessarily represent those of PTC Therapeutics. Thank you.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 5:27:12 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: FW: ACTIV Response Partnership Leadership Team Meeting #3
Attachments: ACTIV Partnership Leadership Team Meeting 20200506 FINAL.pptx

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:13 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 1:11 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

No attachment – can I have the revised version please?

Thanks!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:09 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Santos, Michael (FNIH) [T] [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

I updated slide

Cheryl Melencio

APAR0000013707

Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

b6

fnihi.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Wholley, David (FNIH) [T] b6
Sent: Wednesday, May 6, 2020 1:06 PM
To: Collins, Francis (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6
Cc: Melencio, Cheryl (FNIH) [T] b6; Gonzalez, Nina <ningonzalez@deloitte.com>; Santos, Michael (FNIH) [T] b6
Subject: FW: ACTIV Response Partnership Leadership Team Meeting #3

FYI we were able to catch this just before Cheryl hit send (which is happening now). Amanda's name will appear on the attendee slide.

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) b6
Sent: Wednesday, May 6, 2020 12:57 PM
To: Wholley, David (FNIH) [T] b6
Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) b6
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

Thanks David. I will look forward to attending. Unfortunately, I am unable to make today's meeting as I have an immovable scheduled meeting. Amanda Cohn who is co-leading covid vaccine activities at CDC is available.

Thank you.

From: Wholley, David (FNIH) [T] b6
Sent: Tuesday, May 5, 2020 9:27 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) b6
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

Sorry, Nancy, it is the meeting we have been having every other Wednesday since April 3 with the leadership of all the partners. We are responding to your point made today on our Vx Working Group call (and perhaps earlier, sorry if that is the case) that CDC needs to be included in ACTIV governance. Attached is the latest on participants and agenda. We thought you'd be the best representative for CDC at this meeting given your role and your participation to date in ACTIV, but if you have someone else you think should represent the agency please let me know. N.B., as marked these are clearly in draft form.

David

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) b6
Sent: Tuesday, May 5, 2020 4:52 PM

APAR0000013707

To: Wholley, David (FNIH) [T] [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

Sorry – I'm not sure what meeting this is? Is there an agenda?
Nancy

*Nancy Messonnier, MD
Director
National Center for Immunization and Respiratory Diseases
DDID, CDC*

-----Original Appointment-----

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 4:48 PM
To: Wholley, David (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: ACTIV Response Partnership Leadership Team Meeting #3
When: Wednesday, May 6, 2020 3:30 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: [https://fnih.zoom.us/j/\[b6\]](https://fnih.zoom.us/j/[b6])

Join Zoom Meeting

[https://fnih.zoom.us/\[b6\]](https://fnih.zoom.us/j/[b6])

Meeting ID: [b6]

Password: [b6]

One tap mobile

[b6] US (Germantown)
[b6] US (Chicago)

Dial by your location

[b6] US (Germantown)
[b6] US (Chicago)
[b6] US (New York)
[b6] US (Houston)
[b6] US (San Jose)
[b6] US (San Jose)
[b6] US (Tacoma)

Meeting ID: [b6]

Password: [b6]

Find your local number: [https://fnih.zoom.us/\[b6\]](https://fnih.zoom.us/[b6])

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 5:23:29 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
CC: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]
Subject: RE: ACTIV Org slide for JAMA article.pptx
Attachments: ACTIV Leadership Slides 050620.pptx

Abort!! Please use this version – the first set had one slide and not two.

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 6, 2020 1:21 PM
To: George, Jill (NIH/OD) [E] [b6]
Cc: Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Attached is what will be shown this afternoon to ACTIV leadership – please see two slides.

- CDC addition to the ACTIV leadership team
- Vaccine CTs subgroup

Best,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 11:30 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6] Berkson, Laura (NIH/OD) [E] [b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Almost. One more tweak coming. Use the version that gets shown to ACTIV this afternoon.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 11:02 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Berkson, Laura (NIH/OD) [E] [b6]
Subject: FW: ACTIV Org slide for JAMA article.pptx

Hi Francis,

Is this the version you would like to share for your Senate HELP hearing tomorrow?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 10:37 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire,
Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD)
[E] [b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Yes, I caught those in the master deck. A bit hurried this morning... Here is the revised slide

From: Collins, Francis (NIH/OD) [E] [b6] >
Sent: Wednesday, May 6, 2020 10:32 AM
To: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin,
Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria
(FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
[b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Quick fixes – Gary Gibbons (not Garry). And shouldn't the words "master protocol" appear in the bullets for the Vaccines WG?

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 8:32 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire,
Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD)
[E] [b6]
Subject: ACTIV Org slide for JAMA article.pptx

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 5:16:02 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

Got your email – thank you!

Ashley

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:13 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 1:11 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

No attachment – can I have the revised version please?

Thanks!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:09 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Santos, Michael (FNIH) [T] [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

I updated slide

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

b6

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From: Wholley, David (FNIH) [T] b6
Sent: Wednesday, May 6, 2020 1:06 PM
To: Collins, Francis (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6
Cc: Melencio, Cheryl (FNIH) [T] b6; Gonzalez, Nina <ningonzalez@deloitte.com>; Santos, Michael (FNIH) [T] b6
Subject: FW: ACTIV Response Partnership Leadership Team Meeting #3

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Sent: Wednesday, May 6, 2020 12:57 PM
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Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) b6
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

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Thank you.

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Sent: Tuesday, May 5, 2020 9:27 PM
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David

APAR0000013713

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6]
Sent: Tuesday, May 5, 2020 4:52 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

Sorry – I'm not sure what meeting this is? Is there an agenda?
Nancy

*Nancy Messonnier, MD
Director
National Center for Immunization and Respiratory Diseases
DDID, CDC*

-----Original Appointment-----

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 4:48 PM
To: Wholley, David (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: ACTIV Response Partnership Leadership Team Meeting #3
When: Wednesday, May 6, 2020 3:30 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us/j/> [b6]

Join Zoom Meeting

<https://fnih.zoom.us/j/> [b6]

Meeting ID: [b6]

Password: [b6]

One tap mobile

[b6] US (Germantown)
[b6] US (Chicago)

Dial by your location

[b6] US (Germantown)
[b6] US (Chicago)
[b6] US (New York)
[b6] US (Houston)
[b6] US (San Jose)
[b6] US (San Jose)
[b6] US (Tacoma)

Meeting ID: [b6]

Password: [b6]

Find your local number: <https://fnih.zoom.us/j/> [b6]

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 2:26:49 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Thanks, David! Is the only change to include master protocol for the vaccine group – please see attached. We need to submit this ASAP for use in Francis’ Senate briefing slide for tomorrow.

Thank you,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 8:32 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];
Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire,
Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD)
[E] [b6]
Subject: ACTIV Org slide for JAMA article.pptx

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 1:12:03 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Thanks, David. Cheryl took care of this while we were on the AM call.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 9:10 AM
To: Tabak, Lawrence (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Cheryl, can you please send Larry Tabak any notes requesting attendance at today's LT meeting received from NIHers since the list you sent out at about 6 PM last night? Please copy Ashley Parker on those notes. Thanks, David

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 8:36 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

This was the response I got from Joshua Denny.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Denny, Joshua (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 4:45 PM
To: Melencio, Cheryl (FNIH) [T] [b6] Wholley, David (FNIH) [T] [b6]
Cc: Schully, Sheri (NIH/OD) [E] [b6]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

David and Cheryl,

APAR0000013722

My apologies for the delayed response. Can Sheri still join for us? We (the All of Us Research Program) are also part of the vaccine population subgroup at this time.

thanks

Josh

On May 4, 2020, at 11:18 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Dear Colleagues,

As you may be aware, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership has been moving forward rapidly to address the global pandemic. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines.

Although some ICs have representatives participating in the working groups, we recognize there is a need to keep everyone looped in to the various activities and progress of the partnership, particularly in view of all of the concurrent IC projects about COVID-19. The ACTIV working groups will be delivering their second report to the **ACTIV Leadership Group on Wednesday, May 6, from 3:30-5:00pm**. I am writing to invite the ICDs to listen-in on this meeting. There will be a lot to cover during the meeting and the members of the Leadership Group will be asking the questions. But to give a chance for us NIHers to discuss what has been presented, I am scheduling a separate ICD call for 5:05-5:30pm, immediately following the ACTIV leadership meeting.

If you are available to take part, please send your responses to David Wholley and Cheryl Melencio of FNIH (cc'd here) by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and the ICD follow-up call.

Best regards,
Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 1:11:07 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: Need help on a JAMA article on ACTIV
Attachments: JAMA-Viewpoint-ACTIV-CollinsStoffels-DRAFT-05-04-2020_commentsAP050520-rk fsc_lat.docx

Hi Larry,

I am consolidating your and Cliff's edits but I can't find your CRO language in the attached file – apologies in advance if I am overlooking.

Thank you,
Ashley

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 10:34 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Kolberg, Rebecca (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Re: Need help on a JAMA article on ACTIV

Francis,
Perhaps I missed it but I do not think the article mentions CROs? I think this is a big deal to industry and unless I misunderstand things, it may be wise to include some statement about the intent to survey them as well for capacity/availability. Otherwise it reads very well.
Larry

From: Francis Collins [b6]
Date: Tuesday, May 5, 2020 at 9:38 PM
To: "Parker, Ashley (NIH/OD) [E]" [b6]
Cc: "Kolberg, Rebecca (NIH/OD) [E]" [b6], "George, Jill (NIH/OD) [E]" [b6], "Burklow, John (NIH/OD) [E]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Many thanks, Ashley and Rebecca. Here's my edited version. I've sent a cleaned up copy to Paul Stoffels, to see what he thinks.

Francis

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 7:01 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Kolberg, Rebecca (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Hi Francis,

With many thanks to Rebecca and Jill, please see the attached clean draft of the JAMA article along with the figure and table. These are labeled confidential as we understand the release of the agent prioritization results has not yet been approved.

We can provide the final score for Apremilast in the e-table once we have it and make additional edits as needed.

Thank you,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6] >
Sent: Tuesday, May 5, 2020 7:49 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Kolberg, Rebecca (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
George, Jill (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley,
David (FNIH) [T] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Right. And those slides are due to appear this afternoon.

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 7:23 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Kolberg, Rebecca (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
George, Jill (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley,
David (FNIH) [T] [b6]
Subject: Re: Need help on a JAMA article on ACTIV

Good morning,

I can review what's currently stated and provide some insight but I will need to validate this with the updated timeline in the slide set currently being revised by FNIH.

Thanks,
Ashley

On May 5, 2020, at 7:14 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi Rebecca,

Thanks for this very nice draft. Since Ashley has already seen a draft of the slides for tomorrow, I'm hoping she can provide the needed updates now. Ashley, can you take a crack at that, and then send me a modified version for me to look at tonight?

I'm also attaching a close-to-final draft of an article on COVID vaccine strategy that will appear next week in the NEJM. It mentions ACTIV rather prominently, and needs to be cross referenced.

FC

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 6:25 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]
[b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Hi Francis,

Attached for your review is a draft of your JAMA article. Don't know if you want to look it over now, or if you'd rather wait for me to revise/update when Ashley or someone else sends me over updates from the Working Group meetings on Wednesday. Makes no difference to me!

In addition to the two key locations where you've noted that updates will be needed, there are a few other "late April" and "early May" mentions of deliverables throughout that we will need to address, probably after the WG meeting.

Jill will adapt your second ACTIV slide from the Senate hearing for use as Figure 1 and I'll write a caption. If space allows, we might also propose a Table of the short list of the most promising treatments proposed by the Clinical Therapeutics Working Group.

Thanks,
Rebecca

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Sunday, May 3, 2020 4:26 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]
[b6]; George, Jill (NIH/OD) [E] [b6]
Subject: Need help on a JAMA article on ACTIV

Hi Rebecca,

I'm hoping you can quickly dive into assisting with the development of a draft of the article on ACTIV that JAMA has agreed to consider. It's really important that we get something publishable out there for people to see, as ACTIV has come along very quickly and most people don't even know about it.

Attached is a copy of the e-mail from Howard Bauchner where he offers 1400-1500 words and a Figure.

Also attached is an outline – the beginning and end parts are from me, the middle parts from Ashley. Already at 1371 words, I recognize that some details will need to be dropped.

Also attached is a figure that could be used to explain the structure of ACTIV.

Have a look and let me know what you need to proceed. I'd love to get this submitted this week.

Tx, Francis

<JAMA-Viewpoint-ACTIV-CollinsStoffels-DRAFT-05-04-2020.docx>

<pfCorey4may clean galley .docx>

APAR0000013723

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 12:57:19 PM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Actually FNIH is going to make the changes – will forward to you.

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 6, 2020 8:50 AM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

We are on our AM ACTIV call – will do once we are done here and have captured all the changes.

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 8:48 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: Re: ACTIV Org slide for JAMA article.pptx

Ashley,
FYI, FC is using this as a slide tomorrow in his Senate HELP testimony so we need the changes as soon as possible.
Thanks!
Rebecca

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, May 6, 2020 at 8:43:36 AM
To: "George, Jill (NIH/OD) [E]" [b6]; "Kolberg, Rebecca (NIH/OD) [E]" [b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

I need to make some changes before you work on this – apologies, please standby.

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 6, 2020 8:38 AM
To: George, Jill (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Updated slide/figure for JAMA paper – please see attached.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 8:32 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]

Subject: ACTIV Org slide for JAMA article.pptx

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 12:53:23 PM
To: Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]
Subject: FW: updated IC List for tomorrow's call
Attachments: IC Invitees to May 6 ACTIV Call.docx

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 8:50 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: updated IC List for tomorrow's call

I don't believe there are 50. I just counted there are 37. Here is the updated list.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 8:48 AM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: updated IC List for tomorrow's call

Good morning,

David expressed we have 50 people from NIH – can you please send the updated list with the additional names?

Thanks!
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, May 5, 2020 6:13 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: updated IC List for tomorrow's call

Thanks!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 6:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: updated IC List for tomorrow's call

This is the latest.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 12:53:08 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: FW: updated IC List for tomorrow's call
Attachments: IC Invitees to May 6 ACTIV Call.docx

Thank you, Cheryl.

Ashley

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 8:50 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: updated IC List for tomorrow's call

I don't believe there are 50. I just counted there are 37. Here is the updated list.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]
fnih.org
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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 8:48 AM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: updated IC List for tomorrow's call

Good morning,

David expressed we have 50 people from NIH – can you please send the updated list with the additional names?

Thanks!
Ashley

APAR0000013728

From: Parker, Ashley (NIH/OD) [E]

Sent: Tuesday, May 5, 2020 6:13 PM

To: Melencio, Cheryl (FNIH) [T] [b6]

Subject: RE: updated IC List for tomorrow's call

Thanks!

From: Melencio, Cheryl (FNIH) [T] [b6]

Sent: Tuesday, May 5, 2020 6:12 PM

To: Parker, Ashley (NIH/OD) [E] [b6]

Subject: updated IC List for tomorrow's call

This is the latest.

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

[b6]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 3:02:57 PM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: ACTIV Org slide for JAMA article.pptx

I am asking Francis. Too many sensitivities etc. – he has to make this decision.

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 10:55 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Thanks so much, Ashley! I see this slide is marked “confidential”... want to doublecheck to make sure that it is okay for FC to show the info on this slide at 10 a.m. tomorrow, May 7 before the Senate HELP hearing? Also, we may need to update the ACTIV slides in BRAIN... Jill will send you a link to what’s currently there.

Rebecca

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 10:42 AM
To: George, Jill (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: FW: ACTIV Org slide for JAMA article.pptx

Please see revised ACTIV slide for the JAMA Fig and congressional briefing tomorrow.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 10:37 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Yes, I caught those in the master deck. A bit hurried this morning... Here is the revised slide

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 10:32 AM
To: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Quick fixes – Gary Gibbons (not Garry). And shouldn’t the words “master protocol” appear in the bullets for the Vaccines WG?

FC

APAR0000013732

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 8:32 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire,
Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD)
[E] [b6]
Subject: ACTIV Org slide for JAMA article.pptx

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 2:34:07 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]
Subject: FW: ACTIV Org slide for JAMA article.pptx

FYI.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 10:32 AM
To: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Org slide for JAMA article.pptx

Quick fixes – Gary Gibbons (not Garry). And shouldn't the words "master protocol" appear in the bullets for the Vaccines WG?

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 8:32 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: ACTIV Org slide for JAMA article.pptx

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 10:30:37 PM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]
CC: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Need help on a JAMA article on ACTIV

Me too – need to cook up something to eat!!

Thank you both!
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 6:25 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Hi Ashley,
We are cooking with gas! Attached for you to look over and send along to FC is a clean copy of the modified draft article, plus a Figure and an eTable. We will need to clean up the References a bit closer to submission, but FC knows that's usually the case. One note about the eTable is that it would be nice to include the scale used to rank the potential therapeutic agents, e.g. 0-20.0, or whatever it is. You'll see that's indicated as XX in the heading on the third column. Hope you have a good evening! I need to cook us up some vittles now!!
Rebecca

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 3:57 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Hi Rebecca and Jill,

Please see attached responses and additions.

Rebecca – the focus of the vaccine group has changed drastically and I did not include the reference provided given I removed the original statement. Please feel free to add this back if preferred.

Jill – please see table of therapeutic agents prioritized. As you know this is completely confidential and should not be shared until we receive approval from the leadership group.

I will standby before forwarding to Francis tonight.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, May 5, 2020 1:16 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Responses in blue below.

Thanks,
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 1:14 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Ashley,
I'm in the middle of editing another time-sensitive document right now, so will need keep this brief. Do you have all the info you need right now to fill out all the gaps/update the deliverable times in the draft? YES If so, I recommend that you go ahead and revise the text (using EditTrack) in ways that address the need for updates/fill in the info gaps/answer queries. DOING THIS NOW If you get those revisions done before COB, I'd be happy to give your modified version a quick scan. OK If not, I recommend sending your modified version directly to FC tonight per his request. OK
Rebecca

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 12:41 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Hi Rebecca,

I am working through this now and was planning to share with you within the next hour or so before sending to FC tonight. For the questions you've raised in the draft, did you not want me to share this with you before it goes to FC?

I will attached the draft figure and include the additional reference you've provided below.

For the table: there are concerns about sharing this information publicly and I think this will be discussed with the leadership group tomorrow.

Thank you,
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 12:32 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: FW: Need help on a JAMA article on ACTIV

Hi Ashley,
Just a few follow-up items for the modified version of the JAMA draft that you'll be sending to FC for his review tonight:

b5

Hope this helps!
Rebecca

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 7:15 AM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: Need help on a JAMA article on ACTIV

Hi Rebecca,

Thanks for this very nice draft. Since Ashley has already seen a draft of the slides for tomorrow, I'm hoping she can provide the needed updates now. Ashley, can you take a crack at that, and then send me a modified version for me to look at tonight?

I'm also attaching a close-to-final draft of an article on COVID vaccine strategy that will appear next week in the NEJM. It mentions ACTIV rather prominently, and needs to be cross referenced.

FC

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 6:25 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Hi Francis,

Attached for your review is a draft of your JAMA article. Don't know if you want to look it over now, or if you'd rather wait for me to revise/update when Ashley or someone else sends me over updates from the Working Group meetings on Wednesday. Makes no difference to me!

In addition to the two key locations where you've noted that updates will be needed, there are a few other "late April" and "early May" mentions of deliverables throughout that we will need to address, probably after the WG meeting.

Jill will adapt your second ACTIV slide from the Senate hearing for use as Figure 1 and I'll write a caption. If space allows, we might also propose a Table of the short list of the most promising treatments proposed by the Clinical Therapeutics Working Group.

Thanks,
Rebecca

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Sunday, May 3, 2020 4:26 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: Need help on a JAMA article on ACTIV

Hi Rebecca,

I'm hoping you can quickly dive into assisting with the development of a draft of the article on ACTIV that JAMA has agreed to consider. It's really important that we get something publishable out there for people to see, as ACTIV has come along very quickly and most people don't even know about it.

Attached is a copy of the e-mail from Howard Bauchner where he offers 1400-1500 words and a Figure.

Also attached is an outline – the beginning and end parts are from me, the middle parts from Ashley. Already at 1371 words, I recognize that some details will need to be dropped.

Also attached is a figure that could be used to explain the structure of ACTIV.

Have a look and let me know what you need to proceed. I'd love to get this submitted this week.

Tx, Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 9:01:05 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: <Review & Send> ACTIV Partnership Leadership Slides - For Dr. Collins

That's correct. Nancy is the only CDC rep we have to date. CDC did not participate in the initial April 3rd meeting but was invited later invited to join although I do not think she attended the April 22nd meeting.

Nancy expressed on the vaccine call earlier today the importance of having their leadership involved.

We can discuss if Francis wants to invite a second CDC rep but she is all we have for now.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 4:41 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: <Review & Send> ACTIV Partnership Leadership Slides - For Dr. Collins

Just checking. Am I right?

From: Wholley, David (FNIH) [T]
Sent: Tuesday, May 5, 2020 4:41 PM
To: Gonzalez, Nina <ningonzalez@deloitte.com>; Santos, Michael (FNIH) [T] [b6]
Cc: Elsaid, Olivia <oelsaid@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: <Review & Send> ACTIV Partnership Leadership Slides - For Dr. Collins

No, I thought we decided to invite Nancy as THE CDC rep. I do not think not having a CDC rep on the LT is acceptable.

From: Gonzalez, Nina <ningonzalez@deloitte.com>
Sent: Tuesday, May 5, 2020 3:03 PM
To: Santos, Michael (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Elsaid, Olivia <oelsaid@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: <Review & Send> ACTIV Partnership Leadership Slides - For Dr. Collins

Hi Mike & David –

We kept Nancy on there as we were not sure if the intent was to eventually invite her as a rep for CDC. We can remove her since she is not on the invite tomorrow and it doesn't sound like she will be.

@David are you okay with us removing CDC all together from the slide? I wonder if it will raise a questions.

NG

From: Santos, Michael (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 2:54 PM
To: Gonzalez, Nina <ningonzalez@deloitte.com>; Wholley, David (FNIH) [T] [b6]
Cc: Elsaid, Olivia <oelsaid@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Melencio, Cheryl (FNIH) [T]

b6

Subject: [EXT] RE: <Review & Send> ACTIV Partnership Leadership Slides - For Dr. Collins

Hi Nina and David,

I want to double-check this is deliberate:

On slide 2 ("Attendees for ACTIV Leadership Meeting), we list the CDC and Nancy Messonnier. Nancy Messonnier is not invited to the ACTIV Leadership Meeting: Cheryl just kindly confirmed. As far as I know, there is no CDC representative on the ACTIV LT. Nancy does serve (actively) on the Vaccines WG.

If we're making a conscious decision to keep this as-is, it's okay with me. And I apologize if I'm failing to remember a conversation (or missed it) where we decided this approach. I just thought better safe than sorry. 😊

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Gonzalez, Nina <ningonzalez@deloitte.com>

Sent: Tuesday, May 5, 2020 1:27 PM

To: Wholley, David (FNIH) [T] b6

Cc: Santos, Michael (FNIH) [T] b6; Adam, Stacey (FNIH) [T] b6; Menetski, Joseph (FNIH) [T] b6; Tountas, Karen (FNIH) [T] b6; Anderson, Margaret <marganderson@deloitte.com>; Stratton, Benjamin <bstratton@DELOITTE.com>; Elsaid, Olivia <oelsaid@deloitte.com>; Wachtel, Jonathan <jwachtel@DELOITTE.com>; Alvarez, Rosa Maria <rosalvarez@deloitte.com>; Kim, Elizabeth <elkim@deloitte.com>; Tolman, Brett <btolman@deloitte.com>

Subject: <Review & Send> ACTIV Partnership Leadership Slides - For Dr. Collins

Hi David –

As promised, attached are the latest slides for the ACTIV Leadership meeting tomorrow for Dr. Collins' review. All of the teams have provided their updates and all updates should be incorporated in this version.

One note: We've put all "cut" slides in the Appendix (for now) in case Dr. Collins wants to see what is considered backup. However, we can decide to cut ahead of sending as a pre-read if you'd like.

Please let us know what the outcome of Dr. Collins' review is, and our team will work out a new deadline for this afternoon to ensure we can do a full review today.

All – if you continue to make any edits, please use this version to ensure we are tracking all updates.

Thank you.

Nina

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APAR0000013756

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v.E.1

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 3:10:25 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Master Protocol Subgroup Meeting #13 - Stats ONLY
Location: <https://fnih.zoom.us/j/91812121212> **b6**
Start: 5/6/2020 3:00:00 PM
End: 5/6/2020 4:00:00 PM

Recurrence: (none)

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 8:32:10 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]
Subject: RE: Need help on a JAMA article on ACTIV

Thanks for catching this – I will let FNIH know.

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 4:30 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Thanks!

BTW, I think that first item under Symptomatic/Supportive is Low-Molecular **Weight** Heparin (not Weigh)

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 4:26 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Here is the confidential agent prioritization slide is this is easier to manipulate.

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 4:23 PM
To: George, Jill (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Jill,

Can you please get rid of the third column with the score range? After I finish editing the Text, I'll also have edits to the text of the eTable.

RK

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 4:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Thanks Ashley!

Rebecca: I've found the JAMA instructions for table creation and will follow them. I'll send it to you in a separate Word document. They will make it pretty on their end.

Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 3:57 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]

Cc: George, Jill (NIH/OD) [E] [b6]

Subject: RE: Need help on a JAMA article on ACTIV

Hi Rebecca and Jill,

Please see attached responses and additions.

Rebecca – the focus of the vaccine group has changed drastically and I did not include the reference provided given I removed the original statement. Please feel free to add this back if preferred.

Jill – please see table of therapeutic agents prioritized. As you know this is completely confidential and should not be shared until we receive approval from the leadership group.

I will standby before forwarding to Francis tonight.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]

Sent: Tuesday, May 5, 2020 1:16 PM

To: Kolberg, Rebecca (NIH/OD) [E] [b6]

Cc: George, Jill (NIH/OD) [E] [b6]

Subject: RE: Need help on a JAMA article on ACTIV

Responses in blue below.

Thanks,
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] [b6]

Sent: Tuesday, May 5, 2020 1:14 PM

To: Parker, Ashley (NIH/OD) [E] [b6]

Cc: George, Jill (NIH/OD) [E] [b6]

Subject: RE: Need help on a JAMA article on ACTIV

Ashley,

I'm in the middle of editing another time-sensitive document right now, so will need keep this brief. Do you have all the info you need right now to fill out all the gaps/update the deliverable times in the draft? YES If so, I recommend that you go ahead and revise the text (using EditTrack) in ways that address the need for updates/fill in the info gaps/answer queries. DOING THIS NOW If you get those revisions done before COB, I'd be happy to give your modified version a quick scan. OK If not, I recommend sending your modified version directly to FC tonight per his request. OK
Rebecca

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Tuesday, May 5, 2020 12:41 PM

To: Kolberg, Rebecca (NIH/OD) [E] [b6]

Cc: George, Jill (NIH/OD) [E] [b6]

Subject: RE: Need help on a JAMA article on ACTIV

Hi Rebecca,

I am working through this now and was planning to share with you within the next hour or so before sending to FC tonight. For the questions you've raised in the draft, did you not want me to share this with you before it goes to FC?

I will attached the draft figure and include the additional reference you've provided below.

For the table: there are concerns about sharing this information publicly and I think this will be discussed with the leadership group tomorrow.

Thank you,
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 12:32 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: FW: Need help on a JAMA article on ACTIV

Hi Ashley,
Just a few follow-up items for the modified version of the JAMA draft that you'll be sending to FC for his review tonight:

b5

Hope this helps!
Rebecca

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 7:15 AM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: Need help on a JAMA article on ACTIV

Hi Rebecca,

Thanks for this very nice draft. Since Ashley has already seen a draft of the slides for tomorrow, I'm hoping she can provide the needed updates now. Ashley, can you take a crack at that, and then send me a modified version for me to look at tonight?

I'm also attaching a close-to-final draft of an article on COVID vaccine strategy that will appear next week in the NEJM. It mentions ACTIV rather prominently, and needs to be cross referenced.

FC

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 6:25 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Hi Francis,

Attached for your review is a draft of your JAMA article. Don't know if you want to look it over now, or if you'd rather wait for me to revise/update when Ashley or someone else sends me over updates from the Working Group meetings on Wednesday. Makes no difference to me!

In addition to the two key locations where you've noted that updates will be needed, there are a few other "late April" and "early May" mentions of deliverables throughout that we will need to address, probably after the WG meeting. Jill will adapt your second ACTIV slide from the Senate hearing for use as Figure 1 and I'll write a caption. If space allows, we might also propose a Table of the short list of the most promising treatments proposed by the Clinical Therapeutics Working Group.

Thanks,
Rebecca

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Sunday, May 3, 2020 4:26 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: Need help on a JAMA article on ACTIV

Hi Rebecca,

I'm hoping you can quickly dive into assisting with the development of a draft of the article on ACTIV that JAMA has agreed to consider. It's really important that we get something publishable out there for people to see, as ACTIV has come along very quickly and most people don't even know about it.

Attached is a copy of the e-mail from Howard Bauchner where he offers 1400-1500 words and a Figure.

Also attached is an outline – the beginning and end parts are from me, the middle parts from Ashley. Already at 1371 words, I recognize that some details will need to be dropped.

Also attached is a figure that could be used to explain the structure of ACTIV.

Have a look and let me know what you need to proceed. I'd love to get this submitted this week.

Tx, Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 1:47:23 AM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: Fwd: ACTIV & Warp Speed

Ashley Parker, Ph.D.
Special Assistant to Acting Chief of Staff to the NIH Director
Office of the Director | National Institutes of Health
Tel: [REDACTED] b6

Begin forwarded message:

From: "Meltzer, Abbey (FNIH) [T]" [REDACTED] b6
Date: May 5, 2020 at 9:24:22 PM EDT
To: "Parker, Ashley (NIH/OD) [E]" [REDACTED] b6
Subject: FW: ACTIV & Warp Speed

Dear Ashley,

Please see below for another inquiry that we received.

Best,
Abbey

From: Renaud SEIGNEURIC [REDACTED] b6
Sent: Monday, May 4, 2020 1:42 PM
To: Meltzer, Abbey (FNIH) [T] [REDACTED] b6
Subject: ACTIV & Warp Speed

Dear Abbey Meltzer,

I hope my email finds you well.
I learned about the ACTIV initiative and find it very stimulating and full of hope, thank you. I was wondering how ACTIV was actually connected to the Operation Warp Speed.
Could you let me know please?
Thank you in advance for your reply,
Best regards
Renaud SEIGNEURIC

Renaud SEIGNEURIC, Dr., PhD | Scientific Attaché, Physical Sciences and Nanotechnology, Biomedical Sciences, Translational Research and Innovation

Office for Science and Technology | General Consulate of France in Houston

777 Post Oak Blvd, Suite 600 – Houston, TX 77056 – USA

APAR0000013759

[Office for Science and Technology of the French Embassy in the US](#) | [CONNECT](#)



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/6/2020 1:46:49 AM
To: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: Re: ACTIV & Warp Speed

Hi Abbey,

Received — thank you.

Ashley

On May 5, 2020, at 9:24 PM, Meltzer, Abbey (FNIH) [T] [b6] wrote:

Dear Ashley,

Please see below for another inquiry that we received.

Best,
Abbey

From: Renaud SEIGNEURIC [b6]
Sent: Monday, May 4, 2020 1:42 PM
To: Meltzer, Abbey (FNIH) [T] [b6]
Subject: ACTIV & Warp Speed

Dear Abbey Meltzer,

I hope my email finds you well.

I learned about the ACTIV initiative and find it very stimulating and full of hope, thank you. I was wondering how ACTIV was actually connected to the Operation Warp Speed.

Could you let me know please?

Thank you in advance for your reply,

Best regards

Renaud SEIGNEURIC

Renaud SEIGNEURIC, Dr., PhD | Scientific Attaché, Physical Sciences and Nanotechnology, Biomedical Sciences, Translational Research and Innovation

Office for Science and Technology | General Consulate of France in Houston

777 Post Oak Blvd, Suite 600 – Houston, TX 77056 – USA

[b6] | [LinkedIn](#)

Office for Science and Technology of the French Embassy in the US | [CONNECT](#)

APAR0000013762



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/5/2021 5:02:49 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Koniges, Ursula (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5ae2c3139654bc0b9b95718d516310b-konigesum]
Subject: RE: DDRMS for COS | Attn: Weekly Cabinet Report Submission Due by 3PM TODAY
Attachments: WF 397483 - Selected documents from Incoming folder; WF 397115 - Selected documents from Incoming folder; WF 397455 - Selected documents from Incoming folder; WF 397586 - Selected documents from Incoming folder; WF 397573 - Selected documents from Incoming folder; WF 397608 - Selected documents from Incoming folder; WF 397541 - Selected documents from Incoming folder; WF 397512 - Selected documents from Incoming folder; WF 397467 - Selected documents from Incoming folder; WF 397567 - Selected documents from Incoming folder; WF 397424 - Selected documents from Incoming folder

Oops! Plus the last attached FYI.

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, February 5, 2021 12:01 PM
To: Wolinetz, Carrie (NIH/OD) [E] b6
Cc: Koniges, Ursula (NIH/OD) [E] <
Subject: DDRMS for COS | Attn: Weekly Cabinet Report Submission Due by 3PM TODAY

Hi Carrie,

Please see DDRMS below separated by actions vs. FYI's. **ES has requested any submissions for the weekly Cabinet Report on behalf of COS by 3pm today.**

Need Your Recommendation

WF397483-REMARK: Vetting Request for CoS (ATTN: Dr. Wolinetz) Please review the attached invitation from Emily Chin of the Student Osteopathic Medical Association (SOMA) inviting him to participate as a speaker during their Virtual Spring Convention on Saturday, March 6. **ES sought vetting advice from NIAMS and OCPL; we have not yet received NIAMS recommendation, however, John Burklow defers to your decision.**

WF397115- REMARK: Vetting Request for CoS (ATTN: Dr. Wolinetz) Dr. Collins received the attached invitation from Dr. Lee Fleisher, CMS Chief Medical Officer at the Centers for Medicare and Medicaid Services, inviting him to participate in the 2021 Virtual CMS Quality Conference on March 2-3. **We vetted with OCPL and John Burklow suggested that Dr. Collins appoint a surrogate, however, he did not identify one. ES wanted to check with you to see if you have a suggestion?**

WF397455- REMARK: Vetting Request for Dr. Wolinetz. Please review the attached invitation and respond with your recommendation by February 4, 2021. **Dr. Lauer recommends declining (response attached).** ES will vet with OCPL to follow your recommendation.

WF397586- REMARK: Assigned to CoS (attn Ashley Parker) for necessary action. Writer from Gedeon Richter seeks advice from ACTIV regarding their SARS-CoV-2 therapeutic. **I recommend we have ES sent the standard language to direct companies to the ACTIV preclinical and clinical compound portal for their submission. It's fine to add a line item that says "if you have any questions regarding your submission or need additional information please contact activ_submission@fnihi.org.**

WF397573-REMARK: HHS Report: ES is issuing a recurring data call for the HHS Weekly Cabinet Report. Any items to report for COS? , due to ES by 3:00pm Friday, 2/5.

FYI's

WF397608- OS FYI: The Maryland Congressional Delegation writes to Acting Secretary Norris Cochran and Chief Operating Officer of Operation Warp Speed (OWS) General Gustave Perna requesting that OWS support the Maryland Department of Health's request that the Federal Government aid with vaccine allocations for NIH.

WF397541- REMARK: Hello! ES sent the writer the standard portal acknowledgement.

WF397512- Drs. Rodriguez Vidigal and Barrantes Gallego wrote to Drs. Collins and Fauci to share their hypothesis that diminazene, not yet tested to combat COVID-19 might be an effective treatment for the coronavirus. REMARK: Hello! ES sent the writer the standard portal acknowledgement.

WF397467- Presidential Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking.

WF397567- REMARK: OS: Assigned to CoS and ADEPD as FYI. Assigned to NIAID, CC, ORS, OM, OHR, and OSP for clearance (DUE nlt 3:00pm today, 2/2) to review the strategy outline for Commissioned Corps and the COVID-19 Response, which is for a meeting tomorrow morning (document 1 in the Incoming folder).

WF397424- OS Clearance: Continued Activation of the U.S. Public Health Service Commissioned Corps for the COVID-19 Response

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 4:33:51 PM
To: Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]
Subject: FW: ICD Attendee list for May 6 ACTIV Calls
Attachments: IC Invitees to May 6 ACTIV Call.docx

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 12:24 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: ICD Attendee list for May 6 ACTIV Calls

Here is the latest. If I receive any more will keep you updated.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 3:19:29 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Need help on a JAMA article on ACTIV
Attachments: ACTIV Leadership Slide.pptx

Also, I noticed we updated to leadership slide and a few minor changes were not captured in the revised set.

- Using the BARDA logo for Disbrow and Johnson considering we all fall under HHS
- Two members listed for VA per FC
- Added the name of the agency to the logo for BG Talley

Please see attached.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, May 5, 2020 8:32 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Thanks!

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 8:31 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Need help on a JAMA article on ACTIV

Here you go.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 1:57:16 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: Tried to Reach You - Acorn AI, a Medidata Company
Attachments: FW: Control Arm for COVID-19 Trials

Hi Maria,

We added this yesterday – thank you.

Ashley

From: Freire, Maria (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 9:44 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]
Subject: FW: Tried to Reach You - Acorn AI, a Medidata Company

Ashley, please add these to the database.

FNIHers, FYI.

Thanks, M.

From: Donna Locke [b6]
Sent: Tuesday, May 5, 2020 9:37 AM
To: Freire, Maria (FNIH) [T] [b6]
Subject: Tried to Reach You - Acorn AI, a Medidata Company

Dear Dr. Freire,

I tried to reach you directly this morning, but instead left a voicemail on your Executive Assistant's line.

I wanted to see if I could set up a time for you to learn more about Acorn AI's synthetic control arm.

With 50-60 percent of all COVID-19 trials being run on the Medidata platform, we are able through Acorn AI to provide to the industry a COVID-19 control arm from this data.

In following the news in the industry, I understand that having a control for COVID-19 trials is currently a problem.

May we discuss how Acorn AI, a Medidata could solve this for the industry?

I look forward to speaking with you soon.

Stay safe and healthy,
Donna Locke



Donna Locke – Global Development Advisor – Enterprise

b6

| Cell:

b6

| [Medidata Solutions](#)



New York
NY, USA

350 Hudson, New York City, New York

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Although this is a 1 to 1 direct email if you would like to [Unsubscribe Click Here](#)

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 5/4/2020 3:27:50 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: FW: Control Arm for COVID-19 Trials
Attachments: Fact Sheet-Synthetic Control Database-_20191223.pdf; ASCO-Annual-Meeting_poster_20171020 (1).pdf

Ashley,

For your inclusion in your database.

WG – let me know if this is of any use for you. Otherwise I will reply that I have sent this to the NIH. M.

From: Donna Locke [b6]
Sent: Friday, May 1, 2020 10:22 AM
To: Freire, Maria (FNIH) [T] [b6]
Subject: Control Arm for COVID-19 Trials

Dear Dr. Freire,

I wanted to share with you how Medidata - Acorn AI can provide to the COVID-19 Industry trials a Control Arm for COVID-19.

50 percent of the clinical trials currently being run on COVID-19 utilize the Medidata-Acorn AI platform. With this data that is being collected, we can provide a Synthetic Control Arm to be utilized by the industry as a whole.

Many of your **ACTIV** participants are current customers of Medidata platform.

Rather than having each separate company try to create a Synthetic Control Arm themselves, we have the data. Would it make sense for Medidata-Acorn AI to provide this Control Arm for use industry-wide?

I understand in following COVID-19 news that **the industry is struggling with having a Control Arm to compare trial data results to. We can provide this.**

I have attached a Fact Sheet on our Synthetic Control along with our presentation at ASCO on the actual use of our solution.

We want to help, please tell us how we can.

Continued Health,
Donna Locke



Donna Locke – Global Development Advisor – Enterprise

b6

| Cell:

b6

| [Medidata Solutions](#)



New York
NY, USA

350 Hudson, New York City, New York

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Although this is a 1 to 1 direct email if you would like to [Unsubscribe Click Here](#)

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 11:39:37 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Need help on a JAMA article on ACTIV

Greatly appreciate it – thanks.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 7:39 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Let me see if I can get any updated version from Deloitte. The agenda changed/

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 7:29 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: Re: Need help on a JAMA article on ACTIV

Hi David,

Can I please have a copy of the draft ACTIV leadership slides that were presented yesterday? I understand they are being revised but I need to pull information from the timeline and we need the agenda slide to send the Secretary's office this morning.

Thanks,
Ashley

Begin forwarded message:

From: [b6]
Date: May 5, 2020 at 7:23:22 AM EDT
To: "Collins, Francis (NIH/OD) [E]" [b6]
Cc: "Kolberg, Rebecca (NIH/OD) [E]" [b6], "Burklow, John (NIH/OD) [E]" [b6], "George, Jill (NIH/OD) [E]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6]
Subject: Re: Need help on a JAMA article on ACTIV

Good morning,

I can review what's currently stated and provide some insight but I will need to validate this with the updated timeline in the slide set currently being revised by FNIH.

Thanks,
Ashley

On May 5, 2020, at 7:14 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi Rebecca,

Thanks for this very nice draft. Since Ashley has already seen a draft of the slides for tomorrow, I'm hoping she can provide the needed updates now. Ashley, can you take a crack at that, and then send me a modified version for me to look at tonight?

I'm also attaching a close-to-final draft of an article on COVID vaccine strategy that will appear next week in the NEJM. It mentions ACTIV rather prominently, and needs to be cross referenced.

FC

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 6:25 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]
[b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Hi Francis,

Attached for your review is a draft of your JAMA article. Don't know if you want to look it over now, or if you'd rather wait for me to revise/update when Ashley or someone else sends me over updates from the Working Group meetings on Wednesday. Makes no difference to me!

In addition to the two key locations where you've noted that updates will be needed, there are a few other "late April" and "early May" mentions of deliverables throughout that we will need to address, probably after the WG meeting.

Jill will adapt your second ACTIV slide from the Senate hearing for use as Figure 1 and I'll write a caption. If space allows, we might also propose a Table of the short list of the most promising treatments proposed by the Clinical Therapeutics Working Group.

Thanks,
Rebecca

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Sunday, May 3, 2020 4:26 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]
[b6]; George, Jill (NIH/OD) [E] [b6]
Subject: Need help on a JAMA article on ACTIV

Hi Rebecca,

I'm hoping you can quickly dive into assisting with the development of a draft of the article on ACTIV that JAMA has agreed to consider. It's really important that we get something publishable out there for people to see, as ACTIV has come along very quickly and most people don't even know about it.

Attached is a copy of the e-mail from Howard Bauchner where he offers 1400-1500 words and a Figure.

Also attached is an outline – the beginning and end parts are from me, the middle parts from Ashley. Already at 1371 words, I recognize that some details will need to be dropped.

Also attached is a figure that could be used to explain the structure of ACTIV.

Have a look and let me know what you need to proceed. I'd love to get this submitted this week.

Tx, Francis

<JAMA-Viewpoint-ACTIV-CollinsStoffels-DRAFT-05-04-2020.docx>

<pfCorey4may clean galley .docx>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 8:13:03 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: RE: Covid-19 Vaccine Project Concept

Thanks!

From: Melencio, Cheryl (FNIH) [T] <[REDACTED] b6 >
Sent: Monday, May 4, 2020 3:53 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: Covid-19 Vaccine Project Concept

Hi Ashley

No the concept is contained in his email. There were no attachments

Cheryl Melencio

Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[REDACTED] b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Sent: Monday, May 4, 2020 3:40 PM
To: Melencio, Cheryl (FNIH) [T] <[REDACTED] b6 >
Subject: RE: Covid-19 Vaccine Project Concept

Hi Cheryl,

Did the writer provide an attachment?

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, May 4, 2020 3:31 PM

To: Melencio, Cheryl (FNIH) [T] [b6]

Subject: RE: Covid-19 Vaccine Project Concept

Hi Cheryl,

I will add this response to our spreadsheet and send to our Executive Secretariat's office for response.

Thank you,
Ashley

From: Melencio, Cheryl (FNIH) [T] <[b6]>

Sent: Monday, May 4, 2020 2:02 PM

To: Parker, Ashley (NIH/OD) [E] [b6]

Subject: FW: Covid-19 Vaccine Project Concept

Hi Ashley

This gentleman has been calling me the last couple days trying to send his concept for the ACTIV project. He asked that when you receive it you could confirm receipt. It wasn't coming through to my FNIH email so I had him send it to my personal email. I'm not sure why it doesn't go through.

Thank you

Cheryl

Cheryl Melencio

Administrative Manager, Research Partnerships

Foundation for the National Institutes of Health

[b6]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



----- Forwarded Message -----

From: Howard Jeffrey Bender <[b6]>

To: [b6]

Sent: Monday, May 4, 2020, 01:22:55 PM EDT

Subject: Covid-19 Vaccine Project Concept

Hello, Cheryl -

Thanks for your help this morning. Here's my project concept.

Using available NIH databases, my independent research has found three one-in-a-million nucleotide links between the coronavirus and the human genome, forming the D-loop of tRNA. For the past year my work has been followed by your colleague, Kristofor Langlais [REDACTED] b6, who suggested I continue with lab research needed to confirm my results and speculations. My work is generally described in a YouTube for folks interested in this topic, titled Coronavirus - Using Your DNA Against You. It includes fundamental descriptions but is only about 11 minutes long.

It seems that most vaccine research is focused on finding the right immune cell proteins to keep the coronavirus from infecting human cells in the first place. I'm approaching it differently, with the speculation that at least one of those related nucleotide sequences is part of the reason Covid-19 can become so virulent. As described in the YouTube, if zapping those sequences causes Covid-19 to be a relatively mild infection, perhaps our immune system will form antibodies against it and, by extension, the deadly virus. BTW, I've found different tRNA sequences in both SARS and MERS.

I'm not looking for personal funding, but am asking for a lab researcher to test my concepts and whatever funds are necessary to do it. I suggest four levels, mentioned in the YouTube, with the project stopped for a failure at any level. Those levels are:

1. Using CRISPR or another nucleotide editing system, zap those three sequences in the virus. Whole genome nucleotide sequencing must be done to ensure those sequences have been removed.
2. Using cloned animals, infect one group with the original coronavirus and the other group with the zapped coronavirus. If the zapped animals remain much healthier than the control group, this test will be considered successful.
3. After the healthier animals have fully recovered, infect them with the original coronavirus. If they remain relatively healthy, their immune systems have developed the necessary antibodies, possibly a vaccine from the coronavirus, and this test will be considered successful.
4. Now testing can be done with human subjects, with the hope that humans will also form the necessary antibodies as a self-vaccine, with the researcher watching for any dangerous side effects and other diseases the coronavirus can still create.

If you think my ideas may have merit and can point me to an experimenter to do those tests, we may all defeat this deadly virus.

Thanks for any help you can offer.

Cheers,

Howard

Howard Jeffrey Bender, Ph.D.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 7:36:15 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: RE: Covid-19 Vaccine Project Concept

FYI – found it interesting the writer references Kristofor L., please see below – isn't he still in OSP?

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 2:02 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Covid-19 Vaccine Project Concept

Hi Ashley

This gentleman has been calling me the last couple days trying to send his concept for the ACTIV project. He asked that when you receive it you could confirm receipt. It wasn't coming through to my FNIH email so I had him send it to my personal email. I'm not sure why it doesn't go through.

Thank you

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



----- Forwarded Message -----

From: Howard Jeffrey Bender [b6]
To: [b6]
Sent: Monday, May 4, 2020, 01:22:55 PM EDT
Subject: Covid-19 Vaccine Project Concept

Hello, Cheryl -

APAR0000013944

Thanks for your help this morning. Here's my project concept.

Using available NIH databases, my independent research has found three one-in-a-million nucleotide links between the coronavirus and the human genome, forming the D-loop of tRNA. For the past year my work has been followed by your colleague, Kristofor Langlais b6, who suggested I continue with lab research needed to confirm my results and speculations. My work is generally described in a YouTube for folks interested in this topic, titled Coronavirus - Using Your DNA Against You. It includes fundamental descriptions but is only about 11 minutes long.

It seems that most vaccine research is focused on finding the right immune cell proteins to keep the coronavirus from infecting human cells in the first place. I'm approaching it differently, with the speculation that at least one of those related nucleotide sequences is part of the reason Covid-19 can become so virulent. As described in the YouTube, if zapping those sequences causes Covid-19 to be a relatively mild infection, perhaps our immune system will form antibodies against it and, by extension, the deadly virus. BTW, I've found different tRNA sequences in both SARS and MERS.

I'm not looking for personal funding, but am asking for a lab researcher to test my concepts and whatever funds are necessary to do it. I suggest four levels, mentioned in the YouTube, with the project stopped for a failure at any level. Those levels are:

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3. After the healthier animals have fully recovered, infect them with the original coronavirus. If they remain relatively healthy, their immune systems have developed the necessary antibodies, possibly a vaccine from the coronavirus, and this test will be considered successful.
4. Now testing can be done with human subjects, with the hope that humans will also form the necessary antibodies as a self-vaccine, with the researcher watching for any dangerous side effects and other diseases the coronavirus can still create.

If you think my ideas may have merit and can point me to an experimenter to do those tests, we may all defeat this deadly virus.

Thanks for any help you can offer.

Cheers,

Howard

Howard Jeffrey Bender, Ph.D.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 1:15:38 PM
To: Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]
Subject: FW: I/C directors that will be on Leadership call
Attachments: IC Invitees to May 6 ACTIV Call.docx

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 9:06 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: I/C directors that will be on Leadership call

One of the questions (really an FYI) I did not get to on this morning's call is that so far we have over 50 NIH attendees signed up for the Leadership Team call tomorrow. I know you have told them they are in "listen mode only" but wanted to make sure you know there is nothing in Zoom that allows you to control or prespecify a class of attendees as "listen mode only." Essentially if they start to talk, Joe Menetski can mute them. But that is it. I wanted to make sure you know that and are comfortable with that fact.

David

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 1:47:46 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Meeting with HHS Tomorrow

Hi David,

We recently learned Francis will have a meeting with the Secretary tomorrow afternoon and although we plan to share the meeting summary from the ACTIV leadership meeting 4/22, we would like to share the upcoming agenda for Wednesday's meeting. I understand the slides are being revised but we only need the slide with the agenda - can I have a copy please?

Thank you,
Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/5/2020 12:30:10 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6
Attachments: IC Invitees to May 6 ACTIV Call.docx

Attached is the list I received from Cheryl earlier today.

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 8:12 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

We are not just getting Institute Directors, but half of NIH. Is that the intention?

From: Lankford, David (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 5:59 PM
To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Hello – I would like to listen to the Leadership Group this Wednesday. Thanks,

David W. Lankford
NIH Legal Advisor
Office of the General Counsel
Public Health Division, NIH Branch
NIH Building 31, Room 2B-50
Bethesda, MD 20892-2111
Telephone: [b6]
Fax:
E-Mail:

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you have received this e-mail message in error, please notify the sender immediately.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 11:18 AM
To: ICDDIR-L@LIST.NIH.GOV
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Dear Colleagues,

As you may be aware, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership has been moving forward rapidly to address the global pandemic. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working

groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines.

Although some ICs have representatives participating in the working groups, we recognize there is a need to keep everyone looped in to the various activities and progress of the partnership, particularly in view of all of the concurrent IC projects about COVID-19. The ACTIV working groups will be delivering their second report to the **ACTIV Leadership Group on Wednesday, May 6, from 3:30-5:00pm**. I am writing to invite the ICDs to listen-in on this meeting. There will be a lot to cover during the meeting and the members of the Leadership Group will be asking the questions. But to give a chance for us NIHers to discuss what has been presented, I am scheduling a separate ICD call for 5:05-5:30pm, immediately following the ACTIV leadership meeting.

If you are available to take part, please send your responses to David Wholley and Cheryl Melencio of FNIH (cc'd here) by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and the ICD follow-up call.

Best regards,
Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 5:44:28 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Thank you, Shannon.

Ashley

From: Wooldridge, Shannon (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 1:33 PM
To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Good afternoon,

I'm forwarding the note from Dr. Brennan below since she didn't include you on her response.

Thank you,

Shannon Wooldridge
NIH Executive Secretariat

From: Brennan, Patti (NIH/NLM) [E] [b6]
Sent: Monday, May 4, 2020 11:26 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

I am unable to attend this meeting but would like to have Jerry Sheehan or Steve Sherry represent us in this meeting

Patti
Patricia Flatley Brennan, RN, PhD
Director, National Library of Medicine
National Institutes of Health
US Department of Health and Human Services
Telework Hours: 830-5PM or by appointment Monday through Friday

From: Collins, Francis (NIH/OD) [E] [b6] >
Sent: Monday, May 4, 2020 11:18:07 AM
To: ICDDIR-L@LIST.NIH.GOV <ICDDIR-L@LIST.NIH.GOV>
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Dear Colleagues,

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Best regards,
Francis

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/2/2020 3:17:01 PM
To: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

As you will read, Francis wants to meet with Gary and his leadership team about ACTIV early next week. Please include everyone in the "To" line below; Gary will need to decide who to invite but I imagine that will include him, Amy Paterson, and Steve Goff at a minimum.

Thanks
Larry

From: Francis Collins [b6]
Date: Saturday, May 2, 2020 at 10:57 AM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

I think I need to be involved for this one.

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Saturday, May 2, 2020 9:48 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

Francis,
Can Chris and David Wholley handle this for you? or do you need to be involved?
Larry

From: Francis Collins [b6]
Date: Saturday, May 2, 2020 at 9:13 AM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Adam, Stacey (FNIH) [T]" [b6], "Tountas, Karen (FNIH) [T]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

Sorry that wasn't clear. Need to start with NHLBI. Gary agreed to that.

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Saturday, May 2, 2020 9:03 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T]

[b6]; Austin, Christopher (NIH/NCATS) [E] [b6]

Subject: Re: COVID19-ROA-OTA-FINAL.pdf

To be clear, do you want a special ICDs meeting to review ACTIV with all of them, or a meeting with senior NHLBI staff?

Thanks

Larry

From: Francis Collins [b6]

Date: Saturday, May 2, 2020 at 8:27 AM

To: "Tabak, Lawrence (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]"

[b6], "Wholley, David (FNIH) [T]" [b6], "Adam, Stacey (FNIH) [T]"

[b6], "Tountas, Karen (FNIH) [T]" [b6], "Austin, Christopher (NIH/NCATS) [E]"

[b6]

Subject: RE: COVID19-ROA-OTA-FINAL.pdf

Hi all, (somehow this was stuck in my outbox from yesterday afternoon)

I spoke with Gary Gibbons just now. I'm glad we connected because there is a fairly serious issue here. The NHLBI ROA on host-targeted therapies for COVID-19 was planned before ACTIV came into being. Gary and colleagues thought it was their responsibility to act quickly to harness the clinical trial capacity of PETAL and other networks that they support. That was of course a highly appropriate response to the crisis, and that's how they got their HCQ trial started.

It's clear, however, that Gary is not very well informed about ACTIV. He says David Goff has been giving him occasional updates, but David is very stretched by other duties. I told Gary he is welcome to add another representative so that could be better informed about the Clinical Therapeutics and Clinical Trials Capacity Working Groups.

He says the ROA has created a buzz in his clinical community, who are largely unaware of ACTIV. I tried to fill him in on where we are with the candidate therapeutic prioritization, the master protocol, and the capacity survey. He said that the PIs of NHLBI's networks might not take kindly to a master protocol that they hadn't had input to. I pushed back that this is not the time for academic squabbles that consume months, but a bit of command and control will be needed. He acknowledged that and said he had been preparing the ground for that to happen.

He was clearly suggesting that IC Directors should be better informed about ACTIV. In his case, that's definitely true.

I suggested there should be a meeting early next week where he and his senior staff involved in clinical trials could go over all of these issues and get fully briefed by relevant ACTIV co-chairs about the status of these efforts and the timetables involved.

Can we work on setting that up?

Francis

From: Tabak, Lawrence (NIH/OD) [E] [b6]

Sent: Thursday, April 30, 2020 11:44 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

On it

From: Francis Collins [b6]
Date: Thursday, April 30, 2020 at 11:43 AM
To: "Parker, Ashley (NIH/OD) [E]" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]; "Wholley, David (FNIH) [T]" [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

So this is puzzling. Yes, Larry, please reach out to Gary.

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 11:16 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

Yes, we have him listed on the clinical capacity WG.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 11:11 AM
To: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

First I am seeing also. Isn't David Goff of NHLBI on ACTIV?

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 10:46 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

First I am seeing this. Francis, do you want me to reach out to Gary?

From: "Wholley, David (FNIH) [T]" [b6]
Date: Thursday, April 30, 2020 at 10:34 AM
To: Francis Collins [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

Francis and Larry:

Perhaps I am misunderstanding the intent of this announcement but it seems more than a little duplicative of what we are trying to do in ACTIV. My co-chairs certainly seem to think so. Can someone offer a perspective we can communicate on this please? Thanks, David

From: "Read, Sarah (NIH/NIAID) [E]" [b6] >

Date: April 29, 2020 at 10:45:05 PM EDT

To: "Adam, Stacey (FNIH) [T]" [b6], Eric Hughes [b6]

Subject: FW: COVID19-ROA-OTA-FINAL.pdf

This is interesting. I can't figure out the date of when this was published but it reads like a funding announcement for ACTIV...minus antivirals.

<https://www.nhlbi.nih.gov/sites/default/files/media/docs/COVID19-ROA-OTA-FINAL.pdf>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 4:14:22 PM
To: Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Thanks, Jordan – Cheryl please see note below.

Thank you,
Ashley

From: Gladman, Jordan (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 12:13 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Simon, Dina (NIH/OD) [C] [b6]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Larry already has the pre-call on his calendar.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 12:12 PM
To: Gladman, Jordan (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Simon, Dina (NIH/OD) [C] [b6]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Thanks, Jordan.

Things are moving so fast – I was also notified that there will be a ACTIV pre-meeting today 4-4:30pm. Is this something Dr. Tabak wants to join? Cc'ing Dina as well.

Thank you,
Ashley

From: Gladman, Jordan (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 11:37 AM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Dear Cheryl,

Ashely asked me to send you the Roster we use for IC Directors Meeting. The Director is listed to the far right and the ICO abbreviation is listed on the far left. I already have the main meeting on my calendar from when it was send out originally and will be calling in. If you send me the invite for the 5:05 meeting I will attend that additionally. Let me know if there is anything you need.

Jordan Gladman

Jordan Gladman, PhD
Special Assistant to the NIH Principal Deputy Director
Immediate Office of the Director
National Institutes of Health
Building 1, Suite 108
Bethesda, MD 20892

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 11:18 AM
To: ICDDIR-L@LIST.NIH.GOV
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Dear Colleagues,

As you may be aware, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership has been moving forward rapidly to address the global pandemic. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines.

Although some ICs have representatives participating in the working groups, we recognize there is a need to keep everyone looped in to the various activities and progress of the partnership, particularly in view of all of the concurrent IC projects about COVID-19. The ACTIV working groups will be delivering their second report to the **ACTIV Leadership Group on Wednesday, May 6, from 3:30-5:00pm**. I am writing to invite the ICDs to listen-in on this meeting. There will be a lot to cover during the meeting and the members of the Leadership Group will be asking the questions. But to give a chance for us NIHers to discuss what has been presented, I am scheduling a separate ICD call for 5:05-5:30pm, immediately following the ACTIV leadership meeting.

If you are available to take part, please send your responses to David Wholley and Cheryl Melencio of FNIH (cc'd here) by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and the ICD follow-up call.

Best regards,
Francis

APAR0000013981

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 3:57:59 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: Pre-call for ACTIV Leadership Call #4
Location: see webex below

Start: 5/18/2020 2:30:00 PM
End: 5/18/2020 3:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 3:57:55 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: Pre-call for ACTIV Leadership Call #3
Location: see webex below
Start: 5/4/2020 8:00:00 PM
End: 5/4/2020 8:30:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 10:23:28 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: WF 390650 - Selected documents from Incoming folder
Attachments: 1 Control Arm for COVID-19 Trials.msg; 1a Fact Sheet-Synthetic Control Database-_20191223.pdf; 1b ASCO-Annual-Meeting_poster_20171020 (1).pdf

FYI.

From: Freire, Maria (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 11:28 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E]
Subject: FW: Control Arm for COVID-19 Trials

Ashley,

For your inclusion in your database.

WG – let me know if this is of any use for you. Otherwise I will reply that I have sent this to the NIH. M.

From: Donna Locke [b6]
Sent: Friday, May 1, 2020 10:22 AM
To: Freire, Maria (FNIH) [T] [b6]
Subject: Control Arm for COVID-19 Trials

Dear Dr. Freire,

I wanted to share with you how Medidata - Acorn AI can provide to the COVID-19 Industry trials a Control Arm for COVID-19.

50 percent of the clinical trials currently being run on COVID-19 utilize the Medidata-Acorn AI platform. With this data that is being collected, we can provide a Synthetic Control Arm to be utilized by the industry as a whole.

Many of your **ACTIV** participants are current customers of Medidata platform.

Rather than having each separate company try to create a Synthetic Control Arm themselves, we have the data. Would it make sense for Medidata-Acorn AI to provide this Control Arm for use industry-wide?

I understand in following COVID-19 news that **the industry is struggling with having a Control Arm to compare trial data results to. We can provide this.**

I have attached a Fact Sheet on our Synthetic Control along with our presentation at ASCO on the actual use of our solution.

We want to help, please tell us how we can.

Continued Health,
Donna Locke



Donna Locke – Global Development Advisor – Enterprise

b6

| Cell:

b6

| [Medidata Solutions](#)



New York
NY, USA

350 Hudson, New York City, New York

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 3:38:22 PM
To: Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Control Arm for COVID-19 Trials
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Sent: 5/4/2020 3:37:45 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholley]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: RE: Control Arm for COVID-19 Trials

Hi Maria,

I will add this information to our spreadsheet and forward to our Executive Secretariats' office for response.

Thank you,
Ashley

From: Freire, Maria (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 11:28 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
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Sent: 5/4/2020 3:20:58 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]
Subject: RE: DRAFT EMAIL TO SEND | ICD Invite to ACTIV Leadership Meeting 5/6

OK, noted – thank you.

Ashley

From: Collins, Francis (NIH/OD) [E] { b6 } >
Sent: Monday, May 4, 2020 11:19 AM
To: Parker, Ashley (NIH/OD) [E] { b6 } >
Cc: Tabak, Lawrence (NIH/OD) [E] { b6 } >; Wholley, David (FNIH) [T] { b6 }
Melencio, Cheryl (FNIH) [T] { b6 } >; McManus, Ayanna (NIH/OD) [E] { b6 } >
Subject: RE: DRAFT EMAIL TO SEND | ICD Invite to ACTIV Leadership Meeting 5/6

Just sent. I left out the reference to the co-chairs of the working groups joining the after call with NIH. Since this would include industry reps, I think it's best to just be NIH and FNIH at that point.

FC

From: Parker, Ashley (NIH/OD) [E] { b6 } >
Sent: Monday, May 4, 2020 10:08 AM
To: Collins, Francis (NIH/OD) [E] { b6 } >
Cc: Tabak, Lawrence (NIH/OD) [E] { b6 } >; Wholley, David (FNIH) [T] { b6 } >
Melencio, Cheryl (FNIH) [T] { b6 } >; McManus, Ayanna (NIH/OD) [E] { b6 } >
Subject: DRAFT EMAIL TO SEND | ICD Invite to ACTIV Leadership Meeting 5/6

Hi Francis,

Please see draft email to the ICDs inviting them to attend the ACTIV leadership meeting, 5/6. I spoke with Cheryl and she is anticipating receiving their responses and will send the calendar invites for both the ACTIV leadership meeting and follow-up call.

Thanks,
Ashley

DRAFT EMAIL TO ICDs:

b5

b5

Sincerely,
Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/1/2020 6:25:56 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Covid-19: Proposal for "platform of platform trials"

Received – thank you.

Ashley

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Friday, May 1, 2020 2:21 PM
To: Collins, Francis (NIH/OD) [E] <[b6]> Adam, Stacey (FNIH) [T] <[b6]>
Cc: Parker, Ashley (NIH/OD) [E] <[b6]>
Subject: RE: Covid-19: Proposal for "platform of platform trials"

I see you have passed it on to Stacey as well. We will confer and get back to you. Meanwhile I will make sure Ashley has this so it can go into the opportunity portal.

From: Collins, Francis (NIH/OD) [E] <[b6]>
Sent: Friday, May 1, 2020 1:40 PM
To: Wholley, David (FNIH) [T] <[b6]>; Adam, Stacey (FNIH) [T] <[b6]>
Subject: FW: Covid-19: Proposal for "platform of platform trials"

Would this be of interest?

From: Dirk Reitsma <[b6]>
Sent: Friday, May 1, 2020 1:27 PM
To: Collins, Francis (NIH/OD) [E] <[b6]>
Subject: Covid-19: Proposal for "platform of platform trials"

Dear Dr. Collins,

COVID-19 has provided the impetus to the research community to collaborate as never before. There are now multiple COVID-19 platform trials including platform trials shared between different pharmaceutical companies.

I don't believe any of the individual agencies involved are able to efficiently process, host and analyze the massive amounts of data coming from these disparate sources. We would like to help NIH to centralize COVID-19 resources with the ACTIV consortium.

When I joined PPD from pharma, I realized that a global CRO is one of the few organizations that has the infrastructure to manage such massive amounts of clinical data. I founded our Collaborative Trials Working Group. Using I-SPY2 as a model we designed MICAT, a "next generation" platform trial for melanoma, which now resides with AIM at Melanoma.

Given the urgency of the COVID-19 pandemic, I propose to create a virtual "platform trial of platform trials". The existing and prospective data could be combined in any configuration to support signal detection and prioritization of resources

amongst the many novel approaches. Incorporation of common controls or detection of (non) responsive subgroups is feasible.

My proposal is to utilize PPD's global clinical trials infrastructure to work in concert with NIH infrastructure and resources to manage and host these data. You would be able to rapidly perform exploratory and definitive analyses across the combined data from all the individual sources.

I assume you are very busy. Other than yourself, is there someone else who would see the benefit of facilitating the analysis of the meta-data being generated about managing COVID-19? I am eager to discuss the potential of this approach to see if it is worth pursuing.

With best regards,

Dirk Reitsma.

Dirk J. Reitsma, M.D., Vice President
Therapeutic Area Head Oncology
Global Product Development
PPD.

7101 Wisconsin Avenue
Suite 1100, 11th Floor
Bethesda, MD 20814.

Office: [b6]
Mobile: [b6]
Fax +1 512 685 7353

Executive Assistant

Sue Guy

Email: [b6]
Phone: [b6]
Cell: [b6]

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 9:19:36 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Master Protocol Ad Hoc Meeting
Location: <https://fnih.zoom.us/j/91812345678> **b6**
Start: 5/5/2020 6:00:00 PM
End: 5/5/2020 7:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 9:02:47 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: ACTIV Leadership Call Slide Review
Location: see webex below
Start: 5/4/2020 9:45:00 PM
End: 5/4/2020 10:15:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 8:21:53 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]; Burrus-Shaw, Cyndi (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5bbac95b1f6e4514a299b318030c31f6-shawcy]; Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]
Subject: RE: ICD RSVP List as of 4 p.m. Monday, May 4
Attachments: IC Invitees to May 6 ACTIV Call.docx

Thanks, Cheryl. We can check in tomorrow for an updated confirmed list.

Thank you,
Ashley

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 4:18 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: ICD RSVP List as of 4 p.m. Monday, May 4

This is as of 4 p.m. today. I have added them to Wednesday's call and the aftercall

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fniih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fniih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/4/2020 8:14:34 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]

Subject: Accepted: ACTIV -- FNIH/NIH ICDs Follow-Up
Location: see webex below

Start: 5/6/2020 9:05:00 PM
End: 5/6/2020 9:30:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/1/2020 11:27:59 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: WF 390468 - COVID-19 public-private partnership
Attachments: FW_ COVID-19 public-private partnership.msg

Ashley, FYI.

From: Fischbeck, Kenneth (NIH/NINDS) [E] [b6]
Sent: Thursday, April 23, 2020 10:35 PM
To: Freire, Maria (FNIH) [T] [b6]
Cc: Nath, Avindra (NIH/NINDS) [E] [b6]; Vivian Cheung [b6]; Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: COVID-19 public-private partnership

Thanks for the word, Maria.

I appreciate your attending to it!

Kurt

Sent from my iPhone

On Apr 23, 2020, at 9:35 PM, Freire, Maria (FNIH) [T] [b6] wrote:

I responded to your April 17th e-mail within 6 minutes of receiving it, letting you know that I was sending it to my folks, which I did immediately.

Tachi Yamada, at Vivian Cheung's request also contacted me a day later, Saturday, April 18th, regarding this compound. In my response to Tachi that same afternoon, I clarified the process. Perhaps Vivian did not have a chance to send it to you. It is below.

In addition, immediately upon receipt of the copy of your e-mail to me, Dr. Collins sent your note to the NIAID staff who is also collecting this information in their database. He and I confirmed we had both put it on the list for consideration.

This afternoon, again, I confirmed that this is on the list to be reviewed with the rest of other compounds for prioritization. You will be contacted by a member of the Working Group should your compound be selected.

Maria

From: Freire, Maria (FNIH) [T]
Sent: Saturday, April 18, 2020 6:21 PM
To: Tachi yamada [b6]
Subject: RE: COVID-19 public-private partnership

Hello Tachi! It is always to good to hear from you.

Yes, I have thought over and over again how different things would be if they had paid attention to the recommendations. If nothing else we would have a speedier vaccine process! Do you think the world will finally pay attention after this is done? I have become a skeptic.

As life would have it, I am in Peru. We were on vacation when the government shut down the borders and put the country on lockdown, which is still the case. Unlike travelers and tourists, we have a lovely home here, so we are well, healthy and safe. Safer probably than in the USA, I am very sorry to say. The issue is the return. They have cancelled our flights 3 times already. My ticket is for May 15th now... we will see. If this keeps up, I will seek repatriation through the American Embassy. Nevertheless, being here is the same as teleworking from our home in Maryland – just a bit farther away.

Indeed, ACTIV just launched and we have been front and center, working hand in hand with Francis and the companies. It has been non-stop. I have done this before, as you know, but this is on steroids and at warp speed.

I saw the note from Kurt, which included Vivian and Francis. Let me assure you that my reply was not a polite brush-off – it is part of the process. We have gotten inundated by similar requests, many of which are frivolous or fishing expeditions. Others, like the one below, are taken very seriously.

As background, ACTIV has 4 workstreams, each with a dedicated working group (WG):

1. Standardize and share preclinical evaluation methods in an open forum that allows for comparison and validation
2. Prioritize and accelerate clinical evaluation of therapeutic candidates with near-term potential
3. Maximize clinical trial capacity and effectiveness
4. Advance vaccine development

The WG for workstream 2 is charged with establishing a plan for prioritizing candidates for clinical evaluation. Considerations include a process for making this nimble and fast, prioritizing candidates with different methods of action, rather than multiple candidates with the same methods of action, and leveraging prioritization efforts already done by others, like what is currently being done in the UK (with which we are coordinating). There is no benefit in duplication or redundancy – and there is no time to waste.

What I did immediately upon receiving Kurt's note, as I have done with other similar ones, is to forward it to the person leading this workstream, who is part of the FNIH. They know this is a serious request and it has been placed in the group.

As you know very well, I cannot nor will I try to influence the decision of the WG experts but I am certain that they will review this information and seek additional clarification as needed.

I hope this is helpful and will give Vivian assurances that the note has been placed where it will be appropriately considered.

All the best and stay safe! Maria

From: Tachi yamada <[REDACTED] b6 [REDACTED]>
Sent: Saturday, April 18, 2020 4:57 PM
To: Freire, Maria (FNIH) [T] [REDACTED] b6 [REDACTED]
Subject: Fwd: COVID-19 public-private partnership

Hi Maria - I hope you are well and keeping safe! - I know lots of people were stuck in Peru at the beginning of the pandemic and my hope was that you were not among them - doesn't it seem ironic to you to see all that is going on right now and how some of the many issues might have been avoided if people had paid closer attention to the recommendations of the work that we did on the Commission in 2014? - I read that Francis has set up public-private

initiative to support COVID-19 vaccines (and treatments?) - along these lines Vivian sent me this note and I thought I would reach out to you to learn about how you are managing through this tumultuous time - would it be possible to touch base by phone sometime soon? - many thanks - Tachi

Begin forwarded message:

From: "Cheung, Vivian" [b6]
Date: April 18, 2020 at 7:01:53 AM PDT
To: Tachi yamada [b6]
Subject: Fw: COVID-19 public-private partnership

Hi Tachi,

Following the private-public partnership to develop vaccines against COVID-19, some at the NIH are thinking of developing a similar group to develop treatments. I continue to be involved with NIH and Ionis towards this effort but of course, a broader collaboration will be much more effective. I told our NIH and Ionis colleagues that I would reach out to you to see if you can help with some leadership and coordination. Your experience with international vaccine development and your relationship with FNIH are critically needed. As you can imagine that while this group has lots of passion, real-world experience is not the strength.

Please see emails below - and I can fill in more by phone/ email. I also talked to Mukesh and he said that he would be willing to help administratively in any way he can.

Many thanks
Viv

From: Freire, Maria (FNIH) [T] [b6]
Sent: Friday, April 17, 2020 6:44 PM
To: Fischbeck, Kenneth (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]
Cc: Nath, Avindra (NIH/NINDS) [E]; Cheung, Vivian; Eric Swayze
Subject: RE: COVID-19 public-private partnership

External Email - Use Caution

Thank you, Kurt. I appreciate your note. Let me send it to my folks for follow-up. All the best, Maria

From: Fischbeck, Kenneth (NIH/NINDS) [E] [b6]
Sent: Friday, April 17, 2020 6:38 PM
To: Freire, Maria (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Nath, Avindra (NIH/NINDS) [E] [b6]; Vivian Cheung [b6]
Eric Swayze [b6]
Subject: COVID-19 public-private partnership

It was good to see the announcement today about the public-private partnership for COVID-19 vaccine and therapeutics development.

We have been working with Ionis Pharmaceuticals and NIAID on developing and testing an oligonucleotide therapeutic for COVID-19. Ionis has been very successful in developing oligonucleotide therapy for other diseases, and it has relevant experience with SARS1 and cystic fibrosis.

This collaborative project could be a good fit for the public-private partnership. Please let us know how best to connect with it.

Thanks!

Kurt Fischbeck

Electronic Mail is not secure, may not be read every day, and should not be used for urgent or sensitive issues

From: EDRMS_NO_REPLY@mail.nih.gov <EDRMS_NO_REPLY@mail.nih.gov>

Sent: Friday, May 1, 2020 7:20 PM

To: Parker, Ashley (NIH/OD) [E]: [REDACTED] b6

Subject: WF 390468 - Selected documents from Incoming folder

Attached are the requested documents from WF 390468

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/2/2020 1:29:08 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: JAMA
Attachments: JAMA draft outline 043020 100AM.docx

Resending in case this was lost in your inbox.

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, May 1, 2020 1:10 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: JAMA

Hi Francis,

Please see attached outline for JAMA piece. Is this enough to get you started?

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 8:45 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA

Actually let me give you a little more time – I'm not really going to be able to work on this until Saturday morning. So COB Friday would be fine. 😊

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, April 30, 2020 3:45 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA

COB would be fine

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 3:04 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: JAMA

Hi Francis,

Happy to help, how soon do you need this? – on the call with BARDA for the portal training until 4:30pm.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 2:41 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: JAMA

Hi Ashley,

How about drafting a bulleted outline to get me started?

FC

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, April 30, 2020 2:40 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: JAMA

FYI

From: Howard Bauchner [b6]
Sent: Thursday, April 30, 2020 2:30 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Phil Fontanarosa [b6]
Subject: JAMA

Francis

Wonderful chatting –

Viewpoint – about 1400-1500 words – 5-7 references; can in addition have a table or figure which may help describe the 4 areas – Therapies; Vaccines, RCTs, Pre-clinical.

Do NOT submit but send directly to Phil and me. We will edit it and return it to you for a revision the same day it is received.

Please avoid the royal “we”; quotes, clichés, words like provider and impact.

Look forward to reading it – and sounds quite exciting – and may indeed need these efforts for some sense of normalcy – whatever that maybe - to resume in the Fall.

Stay healthy.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

APAR0000014035

Listen to my chats with authors

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/2/2020 1:10:57 AM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Master List of ACTIV participants

Thanks, Cheryl – have a great weekend!

Ashley

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, May 1, 2020 4:47 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Master List of ACTIV participants

Hi Ashley

Here is the list. I have NOT added William Lee at Gilead ([b6]). I haven't gotten any further guidance. It is on my list of things to check with David about.

Hope you don't have to work all weekend.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/2/2020 12:35:34 AM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: WF 390440 - Selected documents from Incoming folder
Attachments: B01 RE_ Public-private research collaboration.msg; 1 Public-private research collaboration.msg

FYI.

Hi Francis,

Victoria Davey, Assoc Chief Research and Development Officer, Epidemiology and Public Health at the VA has been added to the Clinical Capacity Working group.

https://www.researchgate.net/profile/Victoria_Davey

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 12:41 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6] Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: FW: Public-private research collaboration
Importance: High

What have we already done to incorporate VA into ACTIV?
FC

From: Clancy, Carolyn [b6]
Sent: Monday, April 27, 2020 9:02 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: Public-private research collaboration
Importance: High

Francis,

I read about the initiative / collaboration being led under the auspices of FNIH.

In the spirit of 'we're from the government and here to help', I am writing to express my team's enthusiasm for being a vital participant (we do have 170 medical centers and close to 9 million patients enrolled).

We are collaborating now with NIAID and others – and I am most excited to report that Dr. Ramoni has driven a year long initiative to streamline VA participation in clinical trials.

Many thanks in advance for your consideration.

Hope you and your loved ones are safe and in good health.

Carolyn. – personal cell [b6]

Carolyn M Clancy, MD
Assistant Undersecretary for Health
Discovery, Education and Affiliated Networks
Department of Veterans Affairs
810 Vermont Ave NW
Washington, DC 20420

Assistant: Alicia Bates [b6]

From: EDRMS_NO_REPLY@mail.nih.gov <EDRMS_NO_REPLY@mail.nih.gov>

Sent: Friday, May 1, 2020 8:32 PM

To: Parker, Ashley (NIH/OD) [E] [b6]

Subject: WF 390440 - Selected documents from Incoming folder

Attached are the requested documents from WF 390440

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/1/2020 6:25:56 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Covid-19: Proposal for "platform of platform trials"

Received – thank you.

Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, May 1, 2020 2:21 PM
To: Collins, Francis (NIH/OD) [E] [b6] Adam, Stacey (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Covid-19: Proposal for "platform of platform trials"

I see you have passed it on to Stacey as well. We will confer and get back to you. Meanwhile I will make sure Ashley has this so it can go into the opportunity portal.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, May 1, 2020 1:40 PM
To: Wholley, David (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6]
Subject: FW: Covid-19: Proposal for "platform of platform trials"

Would this be of interest?

From: Dirk Reitsma [b6]
Sent: Friday, May 1, 2020 1:27 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Covid-19: Proposal for "platform of platform trials"

Dear Dr. Collins,

COVID-19 has provided the impetus to the research community to collaborate as never before. There are now multiple COVID-19 platform trials including platform trials shared between different pharmaceutical companies.

I don't believe any of the individual agencies involved are able to efficiently process, host and analyze the massive amounts of data coming from these disparate sources. We would like to help NIH to centralize COVID-19 resources with the ACTIV consortium.

When I joined PPD from pharma, I realized that a global CRO is one of the few organizations that has the infrastructure to manage such massive amounts of clinical data. I founded our Collaborative Trials Working Group. Using I-SPY2 as a model we designed MICAT, a "next generation" platform trial for melanoma, which now resides with AIM at Melanoma.

Given the urgency of the COVID-19 pandemic, I propose to create a virtual "platform trial of platform trials". The existing and prospective data could be combined in any configuration to support signal detection and prioritization of resources

amongst the many novel approaches. Incorporation of common controls or detection of (non) responsive subgroups is feasible.

My proposal is to utilize PPD's global clinical trials infrastructure to work in concert with NIH infrastructure and resources to manage and host these data. You would be able to rapidly perform exploratory and definitive analyses across the combined data from all the individual sources.

I assume you are very busy. Other than yourself, is there someone else who would see the benefit of facilitating the analysis of the meta-data being generated about managing COVID-19? I am eager to discuss the potential of this approach to see if it is worth pursuing.

With best regards,

Dirk Reitsma.

Dirk J. Reitsma, M.D., Vice President
Therapeutic Area Head Oncology
Global Product Development
PPD.

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Sue Guy

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Phone: [b6]
Cell: [b6]

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/1/2020 6:20:04 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: Accepted: ACTIV vaccines discussion
Location: Zoom: <https://fnih.zoom.us/j/91812345678> **b6**
Start: 5/2/2020 8:00:00 PM
End: 5/2/2020 9:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/1/2020 6:19:45 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
Subject: FW: ACTIV vaccines discussion
Location: Zoom: <https://fnih.zoom.us/j/9202020202> b6
Start: 5/2/2020 8:00:00 PM
End: 5/2/2020 9:00:00 PM
Show Time As: Tentative

I did not see you on the thread unless this was intentional.

-----Original Appointment-----

From: Santos, Michael (FNIH) [T] [b6]
Sent: Friday, May 1, 2020 2:15 PM
To: Santos, Michael (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Lane, Cliff (NIH/NIAID) [E]; Mascola, John (NIH/VRC) [E]; Marks, Peter (FDA/CBER); Parker, Ashley (NIH/OD) [E]; Jansen, Kathrin; Lowy, Douglas (NIH/NCI) [E]; Wholley, David (FNIH) [T]
Cc: Wood, Gretchen (NIH/OD) [E]; Conrad, Patricia (NIH/NIAID) [E]; Barasch, Kimberly (NIH/NIAID) [C]; Awwad, David (NIH/NIAID) [C]; Austin, Sarah (NIH/NIAID) [E]; Zottoli, Jessica; Hopps, Markay; Johnson, Maureen (NIH/NCI) [E]; Kozlowski, Mary (NIH/NCI) [C]; Melencio, Cheryl (FNIH) [T]
Subject: ACTIV vaccines discussion
When: Saturday, May 2, 2020 4:00 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Zoom: <https://fnih.zoom.us> [b6]

Meeting to discuss ACTIV vaccines program

Join Zoom Meeting

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Password: b6

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US (Houston)
US (San Jose)

Meeting ID: b6

Meeting ID: _____
Password: **b6**

Find your local number: <https://fnih.zoom.us>

b6

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/2/2020 12:31:47 AM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: WF 390441 Karyopharm with NIH for COVID-19
Attachments: Selinexor in COVID-19 1001_White Paper April 18 FINAL.pdf

FYI.

From: Jackie Quan [b6]
Sent: Monday, April 27, 2020 9:07 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Wolf-Rodda, Julie (FNIH) [T] [b6]
Subject: Karyopharm with NIH for COVID-19

Dear NIH Foundation Team,

Karyopharm is engaged in global, randomized studies to evaluate our small-molecule, oral drug selinexor in patients with advanced COVID-19 infections. These studies are based on substantial clinical and pre-clinical evidence, including new pre-clinical data in models of SARS-CoV-2, supporting a dual mechanism of anti-viral and anti-inflammatory activity through the inhibition of the nuclear export protein XPO1.

We welcome the opportunity to contribute to new research endeavors/collaborations with NIH Foundation in your ACTIV platform.

Key information about the use of selinexor to treat COVID-19 includes:

b4

The attached white paper contains more details on our therapeutic candidate and some of the key data.

We would like to make members of our executive team available to discuss how Karyopharm could made contributions by providing free drug for new research or other, as we strive to advance the public-private partnerships that are so critical to address the ongoing pandemic.

We hope to hear from you soon.

Best Regards,



Jackie Quan
Director, External Research Alliances Liaison
Karyopharm Therapeutics Inc.
[b6] [b6]
85 Wells Avenue, Suite 210, Newton MA 02459
Karyopharm.com

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/2/2020 12:15:17 AM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: WF 390508 - ACTIV Partnership
Attachments: RE_ACTIV Partnership.msg

FYI.

Li—

Sorry for the delayed reply. Thank you for your interest in the ACTIV partnership to speed COVID-19 vaccine and treatment options. As you can imagine, the FNIH and NIH are receiving a large volume of requests similar to yours. To make sure that these requests are appropriately handled, the NIH is tracking and responding to all requests. I have forwarded this message to the NIH on your behalf. In addition I have sent it to our team that is considering agents that might be testing as part of ACTIV. That is the appropriate process for requests like yours right now.

Thanks,
David

From: Li-fang Liang (Contractor) [b6]
Sent: Tuesday, April 28, 2020 2:33 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: Re: ACTIV Partnership

Dear Mr. Wholley,

I am checking back with you to find out whether there is a specific process or application for Fujifilm Pharmaceuticals to participate in the ACTIV partnership program.

Best regards,
Li

Li-fang Liang, PhD
Consultant
Fujifilm Pharmaceuticals, USA

On Thu, Apr 23, 2020 at 1:28 PM Li-fang Liang (Contractor) [b6] wrote:
Dear Mr. Wholley,

I am supporting Fujifilm Pharmaceuticals USA in their development of favipiravir, a broad-spectrum antiviral, as a treatment for COVID-19. Favipiravir is currently being tested against COVID-19 in clinical trials in the US, Japan, China and other countries. The drug has demonstrated activity against SARS-CoV-2 in *in vitro* assay and significantly better treatment effects were reported in favipiravir-treated COVID-19 patients in terms of disease progression and viral clearance when compared with control groups in clinical trials in China. The drug also has an extended safety database (~1500 subjects treated in the two US global Phase 3 influenza trials). Fujifilm Pharmaceuticals is interested in participating in the ACTIV partnership program and a colleague of mine from NIAID provided me with your contact information.

Could you let me know whether there is a specific process or application for participating in the ACTIV partnership program?

Best regards,
Li

Li-fang Liang, PhD
Consultant
Fujifilm Pharmaceuticals, USA

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From: EDRMS_NO_REPLY@mail.nih.gov <EDRMS_NO_REPLY@mail.nih.gov>
Sent: Friday, May 1, 2020 8:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: WF 390508 - Selected documents from Incoming folder

Attached are the requested documents from WF 390508

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/28/2020 10:43:34 PM
To: Li-fang Liang (Contractor) [b6]
Subject: RE: ACTIV Partnership

Li—

Sorry for the delayed reply. Thank you for your interest in the ACTIV partnership to speed COVID-19 vaccine and treatment options. As you can imagine, the FNIH and NIH are receiving a large volume of requests similar to yours. To make sure that these requests are appropriately handled, the NIH is tracking and responding to all requests. I have forwarded this message to the NIH on your behalf. In addition I have sent it to our team that is considering agents that might be testing as part of ACTIV. That is the appropriate process for requests like yours right now.

Thanks,
David

From: Li-fang Liang (Contractor) [b6]
Sent: Tuesday, April 28, 2020 2:33 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: Re: ACTIV Partnership

Dear Mr. Wholley,

I am checking back with you to find out whether there is a specific process or application for Fujifilm Pharmaceuticals to participate in the ACTIV partnership program.

Best regards,
Li

Li-fang Liang, PhD
Consultant
Fujifilm Pharmaceuticals, USA

On Thu, Apr 23, 2020 at 1:28 PM Li-fang Liang (Contractor) [b6] wrote:

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I am supporting Fujifilm Pharmaceuticals USA in their development of favipiravir, a broad-spectrum antiviral, as a treatment for COVID-19. Favipiravir is currently being tested against COVID-19 in clinical trials in the US, Japan, China and other countries. The drug has demonstrated activity against SARS-CoV-2 in *in vitro* assay and significantly better treatment effects were reported in favipiravir-treated COVID-19 patients in terms of disease progression and viral clearance when compared with control groups in clinical trials in China. The drug also has an extended safety database (~1500 subjects treated in the two US global Phase 3 influenza trials). Fujifilm Pharmaceuticals is interested in participating in the ACTIV partnership program and a colleague of mine from NIAID provided me with your contact information.

Could you let me know whether there is a specific process or application for participating in the ACTIV partnership program?

Best regards,
Li

Li-fang Liang, PhD
Consultant
Fujifilm Pharmaceuticals, USA

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From: Ryan Perry [b6]
Sent: 4/28/2020 11:00:37 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]; [b6]; Brian Rowe [b6]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaefe06ebd70-parkeras]
Subject: Re: CIHR, FNIH ACTIV and COVID-19

Hi David,

Thank you for the follow up. No apologies required. Lots of moving parts; however, I have been impressed with the speed at which the research community has responded as well as funders, although I'm sure there are lessons to apply for future.

Cheryl are there specific day/times identified on your end that we can begin to coordinate?

Look forward to connecting soon.

Kind Regards,
Ryan

Ryan Perry, PhD
Associate Scientific Director / Directeur scientifique associé
Institute of Circulatory and Respiratory Health / Institut de la santé circulatoire et respiratoire
Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

E: [b6]
P: [b6]
Suite 602, College Plaza
Rue 8215 112 Street NW
Edmonton, AB, Canada, T6G 2C8

On Apr 28, 2020, at 4:48 PM, Wholley, David (FNIH) [T] [b6] wrote:

Hi Ryan,

By copy of this email to Cheryl Melencio, I am asking if we can set up a one hour call with you and your colleagues to discuss ACTIV, your plans, and whether and how there could be a fit moving forward. In

addition to my FNIH team I am including Ashley Parker from the Office of Science Policy in the NIH Office of the Director. I will send materials as soon as we have something set up. Thanks, David

From: Ryan Perry [b6]
Sent: Thursday, April 23, 2020 4:05 PM
To: Goff, David (NIH/NHLBI) [E] [b6]
Cc: [b6]; Brian Rowe [b6]; Wholley, David (FNIH) [T]
[b6]
Subject: Re: CIHR, FNIH ACTIV and COVID-19
Importance: High

Hi David G.,

Thanks for the connection.

David W. as indicated, there was funding announced to day in Canada that look to share similar goals to that of ACTIV. As we have been in regular communication with our colleagues at NHLBI, we are exploring ways to potentially leverage or align activities, and wanted to reach out to see if you have been in contact with any of our colleagues at CIHR and if not, how we can help make the appropriate linkages to support sharing of information. Look forward to hearing from you.

Kind Regards,
Ryan

Ryan Perry, PhD
Associate Scientific Director / Directeur scientifique associé
Institute of Circulatory and Respiratory Health / Institut de la santé circulatoire et respiratoire
Canadian Institutes of Health Research / Instituts de recherche en santé du Canada
E: [b6]
P: [b6]
Suite 602, College Plaza
Rue 8215 112 Street NW
Edmonton, AB, Canada, T6G 2C8

On Apr 23, 2020, at 12:24 PM, Goff, David (NIH/NHLBI) [E] [b6] wrote:

Ryan and Brian,
The key contact at FNIH for the ACTIV initiative is David Wholley, copied here.

David,
Brian and Ryan are leaders at CIHR in the Institute of Circulatory and Respiratory Health. We are having a series of discussions regarding COVID-19 to learn about activities so we can potentially leverage or align. Today, Brian told me that CIHR has announced an effort that sounds similar in its overall goals to ACTIV. I suggested that additional discussions, that may already be ongoing, might be helpful to fully leverage our joint investments. Please let me know if I can help in any way.

Best regards,
David

David Goff, MD, PhD
Director, Division of Cardiovascular Sciences
National Heart, Lung, and Blood Institute
6705 Rockledge Drive | Suite 309-R
Bethesda, MD 20892

b6

t: @NHLBI_HEARTDir

Doing human subjects research? New policies will affect you! [Learn more.](#)
Looking for NHLBI Clinical Trial Funding Opportunities? [Learn more here.](#)

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/1/2020 1:53:42 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Accepted: ACTIV Response Partnership Leadership Team Meeting #4
Location: <https://fnih.zoom.us/j/91812121212> **b6**
Start: 5/20/2020 7:30:00 PM
End: 5/20/2020 9:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/1/2020 1:53:36 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Accepted: ACTIV Response Partnership Leadership Team Meeting #3
Location: <https://fnih.zoom.us/j/91812121212> **b6**
Start: 5/6/2020 7:30:00 PM
End: 5/6/2020 9:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 5/1/2020 12:37:45 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: HOLD for ACTIV Agent Prioritization Wave 1 Final Discussion Meeting
Location: https://fnih.zoom.us/j/b6
Start: 5/3/2020 7:00:00 PM
End: 5/3/2020 8:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 2:57:09 PM
To: Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]; Wooldridge, Shannon (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385b0c281f104789873e956dc91b7c06-burdense]
Subject: FW: Corvid-19 Vaccine Project Concept
Attachments: RE: Corvid-19 Vaccine Project Concept

FYI.

From: Meltzer, Abbey (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 10:18 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Corvid-19 Vaccine Project Concept

Hi Ashley,

Here is another request that we received related to ACTIV.

Just out of curiosity, do you have an update as to when a link to a portal/database will be up and running to collect this information?

Best,
Abbey

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 4/30/2020 12:51:34 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: RE: Corvid-19 Vaccine Project Concept

Abbey,

Isn't there an NIH mailbox set up for this type of thing? Do you have that?

Joe

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 8:49 AM
To: Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Corvid-19 Vaccine Project Concept

Who should Dr. Bender send his concept to?

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Howard Jeffrey Bender [b6]
Sent: Wednesday, April 29, 2020 8:07 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: Corvid-19 Vaccine Project Concept

Hello, Cheryl -

I have a project concept for a Corvid-19 vaccine and would like to submit it to FNIH for consideration, but am not sure to whom it should go. Could you please send me the name and email address of the appropriate person?

Thanks very much! And stay healthy!

Cheers,

Howard

Howard Jeffrey Bender, Ph.D.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 12:50:39 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV

You're awesome – thank you!

Ashley

From: Tountas, Karen (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 8:48 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV
Importance: High

Good Morning Ashley,

David has approved the response below:

- The question asked in the site-specific survey is “In previous trials, what proportion of participants typically have been members of racial and ethnic minority groups?”
- 110 sites have responded to-date
- The **average proportion reported is 48.6%** with a range of 100 to 0%
- 49 of the 110 sites reported a 50% or greater

Please let us know if you need anything else.

Best regards,
Karen

Karen H. Tountas, PhD
Scientific Program Manager
Foundation for the National Institutes of Health

[b6] | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 8:00 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: Time Sensitive Question from Dr. Collins on ACTIV

Good morning David,

APAR0000014140

As you know, Francis has his briefing with the Congress this morning and needs an answer to the question below ASAP. I'm looping in Stacey and Karen as well.

Thank you,
Ashley

From: Berkson, Laura (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 7:53 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Hallett, Adrienne (NIH/OD) [E] [b6] Higgins, Lauren (NIH/OD) [E] [b6]
Subject: question from FC on ACTIV

Hi Ashley,

As you know, Dr. Collins is briefing E&C committee members today on NIH's COVID-19 activities. When reviewing his prep materials, he asked the following question:
What's the representation of minority communities in the ACTIV clinical trials capacity working group inventory? Find this out from David Wholley/Stacey Adam

Since I know you've been working closely with FNIH on this, would you be able to help us get the answer? Let me know if it would be easier for us to reach out to them directly.

Best,
Laura

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 12:43:11 PM
To: Berkson, Laura (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=adb561ab47e54fdc94e2a54682514434-berksonld]
Subject: FW: Time Sensitive Question from Dr. Collins on ACTIV

FYI.

From: Tountas, Karen (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 8:36 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV

Hi Ashley -- working on a response now and will get it to you momentarily. Karen

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 8:33 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV

Our legislative office needs this information for Dr. Collins ASAP -- can you please acknowledge receipt of this request?

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, April 30, 2020 8:00 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: Time Sensitive Question from Dr. Collins on ACTIV

Good morning David,

As you know, Francis has his briefing with the Congress this morning and needs an answer to the question below ASAP. I'm looping in Stacey and Karen as well.

Thank you,
Ashley

From: Berkson, Laura (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 7:53 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]
Subject: question from FC on ACTIV

Hi Ashley,

As you know, Dr. Collins is briefing E&C committee members today on NIH's COVID-19 activities. When reviewing his prep materials, he asked the following question:

What's the representation of minority communities in the ACTIV clinical trials capacity working group inventory? Find this out from David Wholley/Stacey Adam

Since I know you've been working closely with FNIH on this, would you be able to help us get the answer? Let me know if it would be easier for us to reach out to them directly.

Best,
Laura

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 12:42:34 PM
To: Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV

Thanks, Karen – greatly appreciate it.

Ashley

From: Tountas, Karen (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 8:36 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV

Hi Ashley – working on a response now and will get it to you momentarily. Karen

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 8:33 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV

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Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, April 30, 2020 8:00 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: Time Sensitive Question from Dr. Collins on ACTIV

Good morning David,

As you know, Francis has his briefing with the Congress this morning and needs an answer to the question below ASAP. I'm looping in Stacey and Karen as well.

Thank you,
Ashley

From: Berkson, Laura (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 7:53 AM
To: Parker, Ashley (NIH/OD) [E] [b6]

APAR0000014143

Cc: Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]

Subject: question from FC on ACTIV

Hi Ashley,

As you know, Dr. Collins is briefing E&C committee members today on NIH's COVID-19 activities. When reviewing his prep materials, he asked the following question:

What's the representation of minority communities in the ACTIV clinical trials capacity working group inventory? Find this out from David Wholley/Stacey Adam

Since I know you've been working closely with FNIH on this, would you be able to help us get the answer? Let me know if it would be easier for us to reach out to them directly.

Best,
Laura

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 12:33:47 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Therapeutics Master Protocol Subgroup #14
Location: <https://fnih.zoom.us/j/91812345678> b6
Start: 5/8/2020 5:00:00 PM
End: 5/8/2020 6:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 12:33:41 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Master Protocol Subgroup Meeting #12
Location: <https://fnih.zoom.us> b6
Start: 5/4/2020 5:00:00 PM
End: 5/4/2020 6:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 12:33:38 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Master Protocol Subgroup Meeting #13
Location: https://fnih.zoom.us/j/b6
Start: 5/6/2020 6:00:00 PM
End: 5/6/2020 7:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 10:22:43 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
Subject: RE: NIH staff on ACTIV working groups

Hi Renate,

We discussed co-chair options for the ACTIV exec. comm. Francis is planning to send a note to his preferred co-chair(s) and once this is confirmed I am happy to circle back with you.

Maria and David are also communicating this information with OCPL's FNIH contacts Abbey and Greta.

Thank you,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 12:26 PM
To: Parker, Ashley (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E]
Subject: RE: NIH staff on ACTIV working groups

Much appreciated, Ashley.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 12:17 PM
To: Myles, Renate (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E]
Subject: RE: NIH staff on ACTIV working groups

Hi Renate,

This has not been discussed further, as you know the WH briefing and other urgent items overshadowed. I will raise this issue on our war room call this afternoon – Francis will be the exec. comm. co-chair for NIH, however the industry co-chair still needs to be identified.

I will circle back after the call at 5:30pm today.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 11:57 AM
To: Parker, Ashley (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E]
Subject: RE: NIH staff on ACTIV working groups

Hi Ashley:

Any update on the executive committee and co-chairs?

Renate

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 2:55 PM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

The staff list is correct with the addition of Walter K to the clinical tx group – please see attached.

The executive committee for the overall initiative has not yet been established – the co-chairs will more than likely be Francis and someone from industry but not Cliff Lane. Can they hold off on listing co-chairs for the overall initiative until this is decided?

Thanks,
Ashley

From: Wolinetz, Carrie (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 10:50 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

I don't think we need approvals to have staff listed, but Ashley could probably verify that the list is correct. And I think listing Cliff as co-chair is correct.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 10:48 AM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]
Subject: FW: NIH staff on ACTIV working groups
Importance: High

Hi Carrie and Ashley:

Who needs to okay the listing of our folks names on the FNIH website? We're so used to these kind of things that I really don't think we need approvals, but just double checking. Also, I'm assuming Cliff Lane will be listed as a co-chair of the overall effort?

Renate

From: Gorman, Greta (FNIH) [T] [b6]
Sent: Monday, April 27, 2020 10:44 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Meltzer, Abbey (FNIH) [T] [b6]
Subject: NIH staff on ACTIV working groups

Dear Renate,

We are working to finalize permission from all ACTIV working group members to list their names publicly on our FNIH website.

Attached is the list of working group members who are NIH staff. We heard from some of the NIH staff that this had to go through NIH channels (possibly through Dr. Collins) to grant permission for the NIH employees to be listed.

Will you please pass this through the proper channels to secure NIH's permission to list these names?

Thank you!

Best,
Greta

Greta Gorman
Director of Communications
Foundation for the National Institutes of Health
[b6] fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 2:41:31 PM
To: Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]
CC: Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

FYI.

From: Wholley, David (FNIH) [T] <[REDACTED] b6 >
Sent: Thursday, April 30, 2020 10:34 AM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >; Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 >
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

Francis and Larry:

Perhaps I am misunderstanding the intent of this announcement but it seems more than a little duplicative of what we are trying to do in ACTIV. My co-chairs certainly seem to think so. Can someone offer a perspective we can communicate on this please? Thanks, David

From: "Read, Sarah (NIH/NIAID) [E]" <[REDACTED] b6 >
Date: April 29, 2020 at 10:45:05 PM EDT
To: "Adam, Stacey (FNIH) [T]" <[REDACTED] b6 >, Eric Hughes <[REDACTED] b6 >
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

This is interesting. I can't figure out the date of when this was published but it reads like a funding announcement for ACTIV...minus antivirals.

<https://www.nhlbi.nih.gov/sites/default/files/media/docs/COVID19-ROA-OTA-FINAL.pdf>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/29/2020 9:46:04 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: ES - WF 390352 - Writer (Synlogic) seeks information on grant opportunities for a COVID-19 vaccine (ACTIV).
Attachments: FW: novel approach to COVID-19 vaccine

FYI.

Work Folder Information

Work Folder: WF 390352

Process: FYI

Program Analyst: Whitfield, Michelle D. (NIH/OD) [E]

Due Date:

WF Subject: Writer (Synlogic) seeks information on grant opportunities for a COVID-19 vaccine (ACTIV).

IC: od_cos

From: Kurtz, Caroline

To: James, Stephanie

Remarks: FYI for CoS, NIAID, and OSP. ES sent an acknowledgement email. Thank you.

Dear Ashley,

I am one of the FNIH folks involved in the ACTIV project. I understand you are collating all the unsolicited offers for help on the project, and am forwarding the one below for your files.

Best regards,
Stephanie

Stephanie James, PhD FASTMH

Senior Vice President, Science

Foundation for the National Institutes of Health

b6

www.fnih.org

11400 Rockville Pike Suite 600, North Bethesda, MD 20852

From: Caroline Kurtz { b6 }
Sent: Wednesday, April 22, 2020 6:58 PM
To: James, Stephanie (FNIH) [T] { b6 }
Cc: Michaela Dankova { b6 }
Subject: novel approach to COVID-19 vaccine

Dear Stephanie,

I am reaching out to you as a contact on the FNIH site for information regarding grant opportunities for a COVID-19 vaccine. I lead programs at a small Biopharma company in Cambridge MA called Synlogic Inc (www.synlogictx.com), and we are interested in applying for funding to support development of a vaccine for COVID-19 using our platform. We especially need support to test safety and efficacy of the vaccine in preclinical models under BSL3 conditions. Our proposal is as follows:

Synlogic Inc. proposes to develop a vaccine for the prevention of COVID19 utilizing its synthetic biology platform to engineer probiotic bacteria to express viral antigens and immune activators/adjuvants. This

vaccine will be based on an engineered E. coli Nissle (EcN) bacterial strain that will express viral proteins from SARS-CoV2, the causative agent for COVID-19, and can be administered intranasally to induce protective immunity systemically and at mucosal surfaces. This vaccine can be manufactured in our GMP facilities to produce millions of doses from a single batch. As a lyophilized bacterial cell product, it is expected to have good room temperature stability.

We would be in preclinical development of this vaccine candidate, but already have an engineered E. coli Nissle strain currently in clinical trials for oncology, that can be rapidly adapted for this purpose. The grant would allow us to engineer the strain and test it in preclinical models to get a candidate for clinical studies. Our questions are:

1. Is this project of interest to FNIH? (we could provide an abstract if you need to read more detail to know)
2. Is grant funding available for small businesses?
3. Would a phone call facilitate determining level of interest for this work?
4. What is the process to apply?

Thanks very much for your help and if I should direct my inquiry elsewhere, please advise.

Sincerely,

Caroline Kurtz

Caroline Kurtz, PhD
SVP, Head of Portfolio Strategy and Product Development
Synlogic Inc
301 Binney Street, Suite 402
Cambridge MA, 02142

This message (including any attachments) may contain confidential, proprietary, and/or private information. The information is intended to be for the use of the individual or entity designated above. If you are not the intended recipient of this message, please notify the sender immediately, and delete the message and any attachments. Any disclosure, reproduction, distribution or other use of this message or any attachments by an individual or entity other than the intended recipient is prohibited.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/4/2021 8:09:34 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Follow-Up | Lessons Learned Initiative

Thanks, Francis – this was not at all in need of urgent attention.

Kevin clarified that he and Janet are representing FDA but will ensure this is included on the slides. I gather CDC hasn't been at the table with therapeutics as there are questions of why they should be included in this effort and how? I've provided Kevin with some suggestions and we'll see what happens after this has been given some consideration.

There were plans to include industry/pharm manufacturers towards the end when the team presented the preliminary fact-base and action plan at a public workshop. I've raised your concern and suggested we include industry sooner to gather their perspectives on lessons learned from industry led trials. I've also asked which companies will be invited to participate – industry reps from ACTIV and/or others that may have been recommended.

I will follow-up when I have more to share.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, February 4, 2021 7:27 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Follow-Up | Lessons Learned Initiative

Hi Ashley,

Sorry to have been slow reviewing this.

The goal is meritorious, but I have to say the BCG-driven process feels pretty onerous.

To answer your specific question about other partners, it certainly seems as if CDC and FDA should be represented along with NIH, BARDA, and DoD. And what about industry? How does this "lessons learned" process incorporate their perspectives?

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, February 1, 2021 9:47 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Follow-Up | Lessons Learned Initiative

Hi Francis,

I am touching base to provide a quick update on my meeting with Kevin B. last Friday to discuss the Lessons Learned Initiative. David previously shared a version of slides with the war room, Kevin walked me through the slightly updated slides attached outlining the focus areas (slides 4-5) along with the internal (USG) and external partners (I-SPY, REMAP-CAP, Milken, etc.) the team is engaging for information gathering (BCG is the contractor doing the leg work with Kevin and Stacey as PM leads). This effort is specifically for lessons learned around “therapeutics” and not vaccines.

Kevin is in the process of meeting with agency liaisons identified such as myself and next steps is to meet collectively in Feb. to engage this leadership team, with plans to continue meeting once per month. This group will be responsible for reviewing the results/information gathered and assisting with prioritizing actions. It seems this effort will not only report lessons learned but most importantly develop and prioritize actions (which may include policy reshaping/improvements) to address key challenges identified.

If there are additions/comments to the initial proposal, please let me know and I will circle back with Kevin. I’ve only flagged for us to consider what other USG agencies may be missing or should be included in this effort other than NIH, BARDA, and DOD?; and further asked if CDC should be involved? Assuming Kevin is representing the new USG COVID Response Team (previous OWS), should a liaison from FDA be included or not necessary? Other external partners not listed on slides 5 and 7 that should be engaged to share lessons learned in the therapeutics space?

Thank you,
Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/29/2020 7:37:34 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Accepted: CIHR, FNIH ACTIV and COVID-19
Location: see webex below
Start: 5/5/2020 7:00:00 PM
End: 5/5/2020 8:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/29/2020 10:43:19 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI ES - WF 390428 - Writer seeks information about ACTIV.
Attachments: Re: NIH Question re: California

FYI.

Work Folder Information

Work Folder: WF 390428

Process: FYI

Program Analyst: Whitfield, Michelle D. (NIH/OD) [E]

Due Date:

WF Subject: Writer seeks information about ACTIV.

IC: od_cos

From: Helleman- Desmond, Sue

To: Collins, Francis

Remarks: FYI for OSP, CoS, and NIAID.

It may be - I was wondering where your thinking was on this.

Here is a thought that has been rattling around in my head: what if this "cabinet" spans ACTIV and diagnostics?

You don't need another "Board" in your life right now, do you? A high-level cabinet of advisors who can provide insight, mobilize groups (e.g. academics, local governments, etc) and help you carry the message might be a very good thing, especially if you then have the COVID landscape covered. Just thinking aloud. M.

From: "Collins, Francis (NIH/OD) [E]" <[REDACTED] b6 >
Date: Friday, April 24, 2020 at 7:14:05 PM
To: "Freire, Maria (FNIH) [T]" <[REDACTED] b6 >
Subject: FW: NIH Question re: California

Time to convene a kitchen cabinet?

From: Sue Desmond-Hellmann <[REDACTED] b6 >
Sent: Friday, April 24, 2020 8:05 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >
Subject: NIH Question re: California

Hi Francis,

I hope you are well. I am sheltering in place in California and trying to help folks in the Governor's office tackle COVID19. I read with interest about ACTIV (<https://www.sciencemag.org/news/2020/04/tame-testing-chaos-nih-and-firms-join-forces-streamline-coronavirus-vaccine-and-drug#>), and wanted to ask you what the folks in government or academia here in California can do to support this effort. Also- please let me know if there is a key contact for this effort.

Best,

Sue

Sue Desmond-Hellmann, MD, MPH

Senior Advisor, Bill & Melinda Gates Foundation

Adj. Professor UC San Francisco

APAR0000014177

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 4/25/2020 1:04:54 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: Re: NIH Question re: California

It may be - I was wondering where your thinking was on this.

Here is a thought that has been rattling around in my head: what if this "cabinet" spans ACTIV and diagnostics?

You don't need another "Board" in your life right now, do you? A high-level cabinet of advisors who can provide insight, mobilize groups (e.g. academics, local governments, etc) and help you carry the message might be a very good thing, especially if you then have the COVID landscape covered. Just thinking aloud. M.

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Friday, April 24, 2020 at 7:14:05 PM
To: "Freire, Maria (FNIH) [T]" [b6]
Subject: FW: NIH Question re: California

Time to convene a kitchen cabinet?

From: Sue Desmond-Hellmann [b6]
Sent: Friday, April 24, 2020 8:05 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: NIH Question re: California

Hi Francis,

I hope you are well. I am sheltering in place in California and trying to help folks in the Governor's office tackle COVID19. I read with interest about ACTIV (<https://www.sciencemag.org/news/2020/04/tame-testing-chaos-nih-and-firms-join-forces-streamline-coronavirus-vaccine-and-drug#>), and wanted to ask you what the folks in government or academia here in California can do to support this effort. Also- please let me know if there is a key contact for this effort.

Best,

Sue

Sue Desmond-Hellmann, MD, MPH

Senior Advisor, Bill & Melinda Gates Foundation

Adj. Professor UC San Francisco

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/29/2020 10:38:04 PM
To: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: Accepted: ACTIV Preclinical working group (Friday meeting)
Location: <https://fnih.zoom.us/j/91812345678> **b6**
Start: 4/30/2020 3:00:00 PM
End: 4/30/2020 4:30:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 12:57:37 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Working Group #5
Location: https://fnih.zoom.us/j/b6
Start: 5/7/2020 6:00:00 PM
End: 5/7/2020 7:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 12:57:20 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #7
Location: <https://fnih.zoom.us/j/91812345678> **b6**
Start: 5/5/2020 5:00:00 PM
End: 5/5/2020 6:00:00 PM
Show Time As: Busy

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/29/2020 10:28:34 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FYI: ES - WF 390431 - Writer seeks information to possibly re-purpose oncology drug to treat COVID-19.
Attachments: Fwd: repurposed oncology drug shows in-vitro activity with COVID-19

FYI.

Work Folder Information

Work Folder: WF 390431

Process: FYI

Program Analyst: Whitfield, Michelle D. (NIH/OD) [E]

Due Date:

WF Subject: Writer seeks information to possibly re-purpose oncology drug to treat COVID-19.

IC: od_cos

From: Hosapple, Earle T.

To: Freire, Maria

Remarks: FYI for CoS, OSP, and NIAID.

Ashley,

I will start sending you these. Best, Maria

Begin forwarded message:

From: "Earle T. Holsapple" {b6}
Date: April 26, 2020 at 11:06:38 AM GMT-5
To: "Freire, Maria (FNIH) [T]" {b6}
Cc: Brian Leyland-Jones {b6}
Subject: repurposed oncology drug shows in-vitro activity with COVID-19

Dear Dr. Freire:

We are writing you to seek advice in determining how our clinic-ready, repurposed oncology drug, for use in treating COVID-19, can receive a quick evaluation and, hopefully, be added to the list of therapeutic candidates that meet ACTIV's requisites for consideration.

SciTech Development, LLC (SciTech) is a clinical stage, biopharmaceutical company that has reformulated a well-known and highly-studied, safe retinoid, fenretinide, by overcoming its bioavailability shortcoming. SciTech's lead product, ST-001 nanoFenretinide, is clinic ready (IND in hand for a non-Hodgkin's lymphoma trial).

Published data makes the case for fenretinide and, by inference, ST-001's use in treating COVID-19. Fenretinide and/or ST-001 have recently demonstrated antiviral activity against

SARS-CoV-2 and MERS-CoV-2 and also previously against Dengue, Zika, West Nile, and HIV, viruses. This recorded antiviral activity and its likely immune effects, taken in conjunction with the API's known safety and tolerability profile, makes it an ideal candidate to repurpose for use with COVID-19. We are attaching two one-page documents that quickly summarize the opportunity and MoAs (We suggest these are read before proceeding).

SciTech filed a white paper with both BARDA and NIAID several weeks ago and have heard nothing since. We believe this therapeutic opportunity is too important and timely to be lost in a long review process and warrants immediate consideration.

The development of ST-001 as a drug to treat COVID-19 finds alignment with the medical countermeasure goals of BARDA and the strategic goals of PHEMCE through four key features of our proposition:

1. Early availability to the US healthcare system,
2. Fenretinide and/or ST-001's demonstrated efficacy profile versus Coronaviruses,
3. Readiness of large-scale production upon positive clinical evaluation of ST-001, and
4. Broad impact of proposed clinical investigations beyond COVID-19.

SciTech is presently in negotiations with two large, Midwest healthcare systems to conduct the clinical trial. Last Friday, the company filed a pre-IND application, that cross files with our active IND, for the use of ST-001 in treating COVID-19 patients. We are poised to act quickly and would greatly benefit from government support and/or corporate collaboration.

The rapidly expanding insights into clinical (in particular ICU) care for COVID-19 patients, their pathologic processes and parameters, and SARS-CoV-2 processes unveiled three key drivers of the disease that are direct targets of fenretinide. First, direct inhibition of viral replication would decrease viremia. Second, COVID-19 is strongly associated with increases of both IL-6 and IL-22 immune pathways, reportedly with detrimental implications in some patients (i.e. cytokine storm). SciTech hypothesizes that IL-6 and IL-22 can be controlled by Fenretinide directly inhibiting inflammation and resulting cytokine storm damage. Third, direct communications with critical care physicians and recent research indicate that free radicals might cause organ damage due to an inability to neutralize these. Fenretinide acts as an antioxidant.

Based on the above, we would appreciate guidance on the best approach for receiving serious consideration of our promising COVID-19 therapeutic.

Respectfully seeking your guidance,

Brian Leyland-Jones, MD, PhD
Chief Medical Officer

b6

b6

Earle T. Holsapple
President

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 4/26/2020 4:54:15 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Fwd: repurposed oncology drug shows in-vitro activity with COVID-19
Attachments: image001.png; ATT00001.htm; image002.png; ATT00002.htm; image003.png; ATT00003.htm; image004.png; ATT00004.htm; image005.png; ATT00005.htm; image006.png; ATT00006.htm; image007.png; ATT00007.htm; Quad chart.pdf; ATT00008.htm; CONCEPT PAPER - Reducing ARDS and Pneumonia of Acute Viremia with ST-001 (nanoFENRETINIDE IV).pdf; ATT00009.htm

Ashley,

I will start sending you these. Best, Maria

Begin forwarded message:

From: "Earle T. Holsapple" [b6]
Date: April 26, 2020 at 11:06:38 AM GMT-5
To: "Freire, Maria (FNIH) [T]" [b6]
Cc: Brian Leyland-Jones [b6]
Subject: repurposed oncology drug shows in-vitro activity with COVID-19

Dear Dr. Freire:

We are writing you to seek advice in determining how our clinic-ready, repurposed oncology drug, for use in treating COVID-19, can receive a quick evaluation and, hopefully, be added to the list of therapeutic candidates that meet ACTIV's requisites for consideration.

SciTech Development, LLC (SciTech) is a clinical stage, biopharmaceutical company that has reformulated a well-known and highly-studied, safe retinoid, fenretinide, by overcoming its bioavailability shortcoming. SciTech's lead product, ST-001 nanoFenretinide, is clinic ready (IND in hand for a non-Hodgkin's lymphoma trial).

Published data makes the case for fenretinide and, by inference, ST-001's use in treating COVID-19. Fenretinide and/or ST-001 have recently demonstrated antiviral activity against SARS-CoV-2 and MERS-CoV-2 and also previously against Dengue, Zika, West Nile, and HIV, viruses. This recorded antiviral activity and its likely immune effects, taken in conjunction with the API's known safety and tolerability profile, makes it an ideal candidate to repurpose for

use with COVID-19. We are attaching two one-page documents that quickly summarize the opportunity and MoAs (We suggest these are read before proceeding).

SciTech filed a white paper with both BARDA and NIAID several weeks ago and have heard nothing since. We believe this therapeutic opportunity is too important and timely to be lost in a long review process and warrants immediate consideration.

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2. Fenretinide and/or ST-001's demonstrated efficacy profile versus Coronaviruses,
3. Readiness of large-scale production upon positive clinical evaluation of ST-001, and
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SciTech is presently in negotiations with two large, Midwest healthcare systems to conduct the clinical trial. Last Friday, the company filed a pre-IND application, that cross files with our active IND, for the use of ST-001 in treating COVID-19 patients. We are poised to act quickly and would greatly benefit from government support and/or corporate collaboration.

The rapidly expanding insights into clinical (in particular ICU) care for COVID-19 patients, their pathologic processes and parameters, and SARS-CoV-2 processes unveiled three key drivers of the disease that are direct targets of fenretinide. First, direct inhibition of viral replication would decrease viremia. Second, COVID-19 is strongly associated with increases of both IL-6 and IL-22 immune pathways, reportedly with detrimental implications in some patients (i.e. cytokine storm). SciTech hypothesizes that IL-6 and IL-22 can be controlled by Fenretinide directly inhibiting inflammation and resulting cytokine storm damage. Third, direct communications with critical care physicians and recent research indicate that free radicals might cause organ damage due to an inability to neutralize these. Fenretinide acts as an antioxidant.

Based on the above, we would appreciate guidance on the best approach for receiving serious consideration of our promising COVID-19 therapeutic.

Respectfully seeking your guidance,

Brian Leyland-Jones, MD, PhD
Chief Medical Officer

b6

Earle T. Holsapple

President

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 12:57:17 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Accepted: ACTIV TX-Clinical Agent Prioritization Subgroup Meeting #8
Location: <https://fnih.zoom.us/j/91812345678> **b6**
Start: 5/7/2020 5:00:00 PM
End: 5/7/2020 6:00:00 PM
Show Time As: Busy

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 1/29/2021 1:05:47 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Neaton, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7383b995f643442eb94c59697c2cbc29-neato001.um]; Lundgren, Jens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59d323d1d9274d84b8e8b3046cb81a6b-jens.lundgr]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8801b022ef974bf7bda8fd06f67002cf-qingchen.de]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a221a6336336466793cff9145b09d91b-Contact_f12]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina

[b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]

Subject: Summary of the ACTIV-2/3 Trial Oversight Committee Meeting

Attachments: mpRCT interim presentation_v21-slides 22 and 23 corrected.pdf; Lilly SARS-CoV-2 Neutralizing Antibody Program Update[1].pdf; 2021-01-27_Trial_Oversight_Committee_Meeting_Summary.pdf

Dear ACTIV-2/3 Trial Oversight Committee,

Please find attached the summary of yesterday's meeting. If you have any additions or amendments please let me know.

In addition, please find the link to the colchicine study below and attached the recently made public slides from the ACTIV-4a trial that will be discussed at ACTIV-3 site investigator's meeting and the BLAZE trial results that were presented by Lilly on Wednesday.

<https://medrxiv.org/cgi/content/short/2021.01.26.21250494v1>

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Direct: [b6] | Mobile: [b6]

fnihi.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 9/2/2020 3:41:15 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: RE: C3PO trial

Thanks, Ashley,

I will let OWS know this response.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, September 2, 2020 10:59 AM
To: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]
Subject: RE: C3PO trial

Hi Stacey,

Please see the response from the HHS, Jessica Roach in ADM Giroir's office whom Francis and I have been in contact with regarding the supply of Abbott machines provided by the ADM.

The question has come up on whether those machines will be given to the sites or collected back up after the trial? **"No. The one instance where we collected the instruments was a special case. The expectation is that those who receive instruments will keep them, though we cannot guarantee the supply of any tests that they would like to procure on their own directly from Abbott."**

Regarding information that is in the contracts Amy Patterson, cc'd here for C3PO. The NCATS funded CP trials (Einstein, Houston, UMiami, and Vanderbilt) did not receive Abbott machines and test, only the outpatient CP trials (C3PO and the JHU trial which is funded by DOD).

Please let me know if you need anything else.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, September 2, 2020 9:50 AM
To: Wholley, David (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: C3PO trial

Thanks, David,

The HHS team is pretty interested in us finding out if this in the contracts with the sites about USG provided equipment. And finding it out quickly, Ashley, if you do not know, do you know who at NHLBI and NCATS could be contacted to find out?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, September 2, 2020 9:38 AM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: C3PO trial

Ashley may know, I don't. Copying her.

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, September 2, 2020 9:25 AM
To: Wholley, David (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: C3PO trial

Hi David,

Do you know what guidance was given to the convalescent plasma sites that received the machines?

If we don't know, I will let Sheri know that we will need to send a letter marking that they should be returned.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Parker, CAPT Sheri (HHS/IOS) [b6]
Sent: Wednesday, September 2, 2020 9:11 AM

To: Homer, Mary (OS/ASPR/BARDA) [b6]
Cc: Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Adam, Stacey (FNIH) [T] [b6]
Bujaki, Becky (HHS/IOS) [b6]
Subject: RE: C3PO trial

Hi Mary,

It is my understanding that they are property of the government and would need to be returned. I know for ACTIV-3 they are tagging them as government property for items sent to the ACTG network and the PPD funded sites.

These came via the SNS to you, my assumption is they would return to the SNS.

I've added my logistic counterpart to the query as well as Stacey who assisted in the request.

v/r,
Sheri

Sheri Parker, PMP, PhD
CAPT, MSC, USN
Therapeutics Clinical Operations Director
Operation Warp Speed
Cell: [b6]

From: Homer, Mary (OS/ASPR/BARDA) [b6]
Sent: Tuesday, September 1, 2020 3:58 PM
To: Parker, CAPT Sheri (HHS/IOS) [b6]
Cc: Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]
Subject: C3PO trial

Capt Parker,

Do you happen to know who authorized giving the Abbott machines to the clinical sites for C3PO – the question has come up on whether those machines will be given to the sites or collected back up after the trial?

Mary J. Homer, PhD
Chief
Radiological and Nuclear Countermeasures
Division of Chemical, Biological, Radiological, and Nuclear Countermeasures
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services
O'Neill Federal Office Building, 24K13
(Classic BLUE – PANTONE 19-4052; RGB 52:86:139))

Office [b6]
Work Mobile [b6]
[b6]

<< OLE Object: Picture (Device Independent Bitmap) >>



Mailing address:
330 Independence Ave, SW, Room G644
Washington, DC 20201

APAR0000005808

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Note to contractors: nothing in this e-mail is intended to constitute contractual direction or to impact current negotiated cost, price, or schedule contained in the contract. If the contractor believes there is an impact, the contractor must disregard that portion of the communication and contact the Contracting Officer for direction.

From: Lisa Oxton [Lisa.Oxton@ppdi.com]
Sent: 8/12/2020 12:24:20 PM
To: Javan, Arzhang (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1d19903ce334e38821395d7aa1327c4-javanarc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; Angie Greer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8432678a3114b55a34879c251520a82-angela.gree]; BambraStokes [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcf21dfe19e94b8faa422393f4c60815-Bambra.Stok]; Jackie Givens [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=380ee876cf2644198aa8df1c038a2edd-JackieGiven]; Wong, Michelle (NIH/NIAID) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98b2c9991a354e7087e47c14df97227e-wongmic]; Jessica Holden [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4c1d7d99e924ae4bb0ee6e07ebe8e43-JessicaHold]; William Murtaugh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6cbb50e37aaf4f238c6645de3eccdf8c-WilliamMurt]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Good morning-

I am copying in Will, as I was working with him on an effort to get GeneXpert instruments and cartridges to sites. I believe Will has a list of network sites that have requested those.

Is this a separate effort for the Abbott machines and will some sites end up receiving both instruments?

Thanks for shedding some light on the process and efforts.

Kind regards,
Lisa

Lisa Oxton, CCRA, MSPM, PMP
Project Manager
Government & Public Health Services

Providing strategic partnership and local expertise in clinical research to protect and enhance global public health.

Phone [b6]
Cell [b6]
Fax +1 215 827 5684
[b6]



PPD
Home Based Support –
Madison, Wisconsin

From: Javan, Arzhang (NIH/NIAID) [E] [b6]
Sent: Wednesday, August 12, 2020 7:19 AM
To: Adam, Stacey (FNIH) [T] [b6]; Currier, Judith, M.D. [b6]; Smith, David [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Angela Greer [b6]; Bamba Stokes [b6]; Lisa Oxtan [b6]; Jackie Givens [b6]; Wong, Michelle (NIH/NIAID) [C] [b6]; Jessica Holden [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

This email originated outside PPD. Please use caution before clicking links.

Thanks a lot Stacey.

I am copying in our PPD colleagues who have more granular details on this list of sites and the status of this list.

Angie or anyone else from PPD, can you please review the request below and provide a status update.

Thanks a lot.

Best,
Cyrus

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 7:30 AM
To: Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Hi All,

Sorry for the duplicate emails, but I need to update the time we need these by. Could you please send them by 11am ET so Ashley will have time to compile with the others and have to OWS by noon.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

APAR0000005911

From: Adam, Stacey (FNIH) [T]

Sent: Wednesday, August 12, 2020 7:26 AM

To: Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E]

[b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]

Cc: Parker, Ashley (NIH/OD) [E] [b6]

Subject: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Importance: High

Dear Judy, Davey, Peter, and Cyrus (since I know Peter is away),

Would it be possible for you to get me the addresses of the sites that you had wanted to receive the Abbott Machines for rapid testing?

Dr. Collins needs to send this to the OWS team by noon today if the machines are going to get shipped out this week.

I am cc'ing Ashley Parker who will help to get this list combined with those from the other NIH trials.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: [b6] Mobile: [b6]

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



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From: Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]
Sent: 8/24/2020 12:31:33 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ACTIV Daily Update 20200824.pptx

Mayo website

Focus areas

- **Convalescent plasma.** Dr. Joyner is leading a national program sponsored by the U.S. Government to coordinate the collection and distribution of COVID-19 convalescent plasma for the treatment of individuals with severe or life-threatening disease.

Professional highlights

- Principal investigator, Expanded Access to Convalescent Plasma for the Treatment of Patients With COVID-19, FDA, 2020

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, August 24, 2020 7:30 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: ACTIV Daily Update 20200824.pptx

For this morning's war room, Monday August 24.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/13/2020 3:24:45 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Thanks, Ashley,

We appreciate the follow-up. Thank you.

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 11:19 PM
To: Kim, Peter (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Hi Peter and Stacey,

Dropping everyone else off for the moment – not sure who really needs this info.

Please see the ACTIV-2 order schedule for the Abbott machines and tests below. The shipping POC, [b6] should receive the initial order of 17 machines and 15 kits (360 tests) by Monday, 8/17 and the remaining to follow each week. ADM Giroir's office also mentioned the POC will receive the tracking numbers, order confirmations, and may be contacted by Abbot for training/support if needed.

		12-Aug	16-Aug	23-Aug	30-Aug	6-Sep	13-Sep	20-Sep	Total
Shipping Address	ACTIV-2 outpatient trial of monoclonal Ab								Total
[b6]	Machines	17	15	13	10	0	0	0	55
	Kits	15	20	20	20	23	23	14	135

b6

Test

360

480

480

480

552

552

336

3240

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]

Sent: Wednesday, August 12, 2020 9:03 AM

To: Kim, Peter (NIH/NIAID) [E] b6; Javan, Arzhang (NIH/NIAID) [E] b6 Adam, Stacey (FNIH) [T] b6 Judy Currier b6 Davey Smith b6 Angie Greer b6 BambraStokes b6 Lisa Oxtan b6 Jackie Givens b6 Wong, Michelle (NIH/NIAID) [C] b6 Jessica Holden b6 Erhardt, William (HHS/IOS) b6

Cc: William Murtaugh b6 Grace Aldrovandi b6 Alexis Sexton b6 Parker, CAPT Sheri (HHS/IOS) b6 Church, Elizabeth (NIH/NIAID) [E] b6

Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Hi Peter,

Thank you for confirming.

Best,
Ashley

From: Kim, Peter (NIH/NIAID) [E] b6

Sent: Wednesday, August 12, 2020 9:01 AM

To: Parker, Ashley (NIH/OD) [E] b6; Javan, Arzhang (NIH/NIAID) [E] b6 Adam, Stacey (FNIH) [T] b6 Judy Currier b6 Davey Smith b6 Angie Greer b6 BambraStokes b6 Lisa Oxtan b6 Jackie Givens b6 Wong, Michelle (NIH/NIAID) [C] b6 Jessica Holden b6 Erhardt, William (HHS/IOS) b6

Cc: William Murtaugh b6 Grace Aldrovandi b6 Alexis Sexton b6 Parker, CAPT Sheri (HHS/IOS) b6 Church, Elizabeth (NIH/NIAID) [E] b6

Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Hi Ashely, all,

Thanks for the notice. I can confirm that the attached info is correct and that the machines and cartridges should be delivered to the distribution center below.

I'd like to note that it's extremely important that the b6 info is listed prominently on the label.

b6

APAR0000005949

b6

Thanks,
Peter

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Wednesday, August 12, 2020 8:40 AM
To: Javan, Arzhang (NIH/NIAID) [E] b6; Adam, Stacey (FNIH) [T] b6; Judy Currier
b6; Davey Smith b6; Kim, Peter (NIH/NIAID) [E]
b6; Angie Greer b6; BambaStokes b6; Lisa Oxtan
b6; Jackie Givens b6; Wong, Michelle (NIH/NIAID) [C]
b6; Jessica Holden b6; Erhardt, William (HHS/IOS)
b6

Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Hi Cyrus,

OWS has agreed to supply the attached number of machines and tests, however shipments will occur on a weekly basis until you have received the complete supply.

We only needed the addresses to ensure the supplies arrive at the correct location.

Thanks,
Ashley

From: Javan, Arzhang (NIH/NIAID) [E] b6
Sent: Wednesday, August 12, 2020 8:31 AM
To: Parker, Ashley (NIH/OD) [E] b6; Adam, Stacey (FNIH) [T] b6; Judy Currier
b6; Davey Smith b6; Kim, Peter (NIH/NIAID) [E]
b6; Angie Greer b6; BambaStokes b6; Lisa Oxtan
b6; Jackie Givens b6; Wong, Michelle (NIH/NIAID) [C]
b6; Jessica Holden b6; Erhardt, William (HHS/IOS)
b6

Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Thanks Ashley. Yes this is likely where all supplies would likely be sent but b6 from PPD will have more real time information on the status of this list and our request for these important machines.

I will do my best to connect with the appropriate people before the deadline and provide an appropriate update by the requested time.

This will help ensure this important process is carried out efficiently and correctly.

Thanks.

Cyrus

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Sent: Wednesday, August 12, 2020 8:23 AM
To: Javan, Arzhang (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Angie Greer [b6]; BambraStokes [b6]; Lisa Oxton [b6]; Jackie Givens [b6]; Wong, Michelle (NIH/NIAID) [C] [b6]; Jessica Holden [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Below is the information we received for shipping. Is this address OK?

b6

Thank you,
Ashley

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Sent: Wednesday, August 12, 2020 8:19 AM
To: Adam, Stacey (FNIH) [T] [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Angie Greer [b6]; BambraStokes [b6]; Lisa Oxton [b6]; Jackie Givens [b6]; Wong, Michelle (NIH/NIAID) [C] [b6]; Jessica Holden [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Thanks a lot Stacey.

I am copying in our PPD colleagues who have more granular details on this list of sites and the status of this list.

[b6] or anyone else from PPD, can you please review the request below and provide a status update.

Thanks a lot.

Best,
Cyrus

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 7:30 AM
To: Judy Carrier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E]
[b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

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Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

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[b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
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Importance: High

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I am cc'ing Ashley Parker who will help to get this list combined with those from the other NIH trials.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] Mobile: [b6]
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

APAR0000005949



From: Kim, Peter (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C48148E476824CE893260ACF33B0F774-KIMP2]
Sent: 8/13/2020 3:48:55 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Thanks!

On Aug 13, 2020, at 11:30 AM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Hi Peter,

Yes, that is correct – thanks!

Ashley

From: Kim, Peter (NIH/NIAID) [E] [b6]
Sent: Thursday, August 13, 2020 11:28 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Ashley, thanks again. Can I confirm that these are coming from National Stockpile and we do not need to pay for them?

Thanks,

Peter

On Aug 12, 2020, at 11:18 PM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Hi Peter and Stacey,

Dropping everyone else off for the moment – not sure who really needs this info.

Please see the ACTIV-2 order schedule for the Abbott machines and tests below. The shipping POC, [b6] should receive the initial order of 17 machines and 15 kits (360 tests) by Monday, 8/17 and the remaining to follow each week. ADM Giroir's office also mentioned the POC will receive the tracking numbers, order confirmations, and may be contacted by Abbot for training/support if needed.

		12- Aug	16- Aug	23- Aug	30- Aug	6- Sep	13- Sep
--	--	------------	------------	------------	------------	-----------	------------

Shipping Address	ACTIV-2 outpatient trial of monoclonal Ab					
b6	Machines	17	15	13	10	0
	Kits	15	20	20	20	23
	Test	360	480	480	480	552

Thanks,
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b6; Jackie Givens b6 Wong, Michelle
(NIH/NIAID) [C] b6; Jessica Holden b6;
Erhardt, William (HHS/IOS) b6
Cc: William Murtaugh b6; Grace Aldrovandi
b6; Alexis Sexton b6; Parker,
CAPT Sheri (HHS/IOS) b6; Church, Elizabeth (NIH/NIAID) [E]
b6
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid
Machines

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To: Parker, Ashley (NIH/OD) [E] b6; Javan, Arzhang (NIH/NIAID)
[E] b6; Adam, Stacey (FNIH) [T] b6 Judy Currier
b6 Davey Smith b6; Angie Greer
b6 BambraStokes b6; Lisa Oxton
b6 Jackie Givens b6 Wong, Michelle
(NIH/NIAID) [C] b6; Jessica Holden b6;
Erhardt, William (HHS/IOS) b6
Cc: William Murtaugh b6; Grace Aldrovandi
b6; Alexis Sexton b6; Parker,

CAPT Sheri (HHS/IOS) [b6]; Church, Elizabeth (NIH/NIAID) [E]

[b6]

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[b6]; Judy Currier [b6]; Davey Smith
[b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Angie
Greer [b6]; BambraStokes [b6]; Lisa
Oxton [b6]; Jackie Givens [b6]; Wong,
Michelle (NIH/NIAID) [C] [b6]; Jessica Holden [b6]
[b6]; Erhardt, William (HHS/IOS) [b6]
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Sent: Wednesday, August 12, 2020 8:31 AM

To: Parker, Ashley (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T]
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Oxton [b6]; Jackie Givens [b6]; Wong,
Michelle (NIH/NIAID) [C] [b6]; Jessica Holden [b6]
[b6]; Erhardt, William (HHS/IOS) [b6]

Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Thanks Ashley. Yes this is likely where all supplies would likely be sent but [b6] from PPD will have more real time information on the status of this list and our request for these important machines.

I will do my best to connect with the appropriate people before the deadline and provide an appropriate update by the requested time.

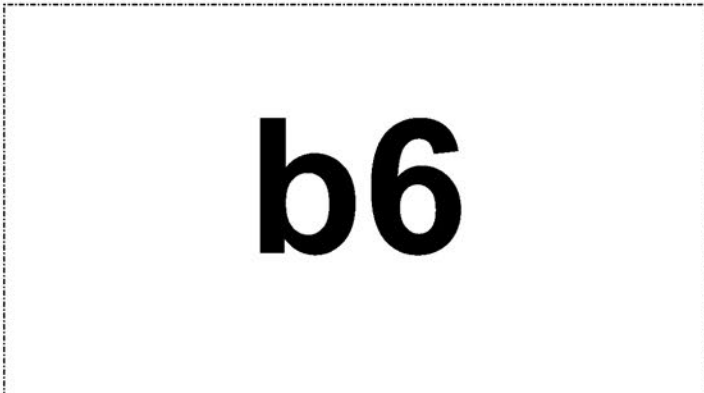
This will help ensure this important process is carried out efficiently and correctly.

Thanks.

Cyrus

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Sent: Wednesday, August 12, 2020 8:23 AM
To: Javan, Arzhang (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T]
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Michelle (NIH/NIAID) [C] [b6]; Jessica Holden [b6]
[b6]
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To: Adam, Stacey (FNIH) [T] [b6]; Judy Currier
[b6] Davey Smith [b6] Kim, Peter
(NIH/NIAID) [E] [b6] Angie Greer [b6];
BambraStokes [b6] Lisa Oxtan [b6]; Jackie
Givens [b6] Wong, Michelle (NIH/NIAID) [C]
[b6] Jessica Holden [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid
Machines

Thanks a lot Stacey.

I am copying in our PPD colleagues who have more granular details on this list of sites
and the status of this list.

[b6] or anyone else from PPD, can you please review the request below and provide a
status update.

Thanks a lot.

Best,
Cyrus

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 7:30 AM
To: Judy Currier [b6]; Davey Smith
[b6] Kim, Peter (NIH/NIAID) [E] [b6]; Javan,
Arzhang (NIH/NIAID) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid
Machines

Hi All,

Sorry for the duplicate emails, but I need to update the time we need these by. Could
you please send them by 11am ET so Ashley will have time to compile with the others
and have to OWS by noon.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Wednesday, August 12, 2020 7:26 AM

To: Judy Currier [b6]; Davey Smith
[b6]; Kim, Peter (NIH/NIAID) [E] [b6] Javan,
Arzhang (NIH/NIAID) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines
Importance: High

Dear Judy, Davey, Peter, and Cyrus (since I know Peter is away),

Would it be possible for you to get me the addresses of the sites that you had wanted to receive the Abbott Machines for rapid testing?

Dr. Collins needs to send this to the OWS team by noon today if the machines are going to get shipped out this week.

I am cc'ing Ashley Parker who will help to get this list combined with those from the other NIH trials.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] Mobile: [b6]
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852
<image001.jpg>

<image002.jpg>

<image003.jpg>

<image004.jpg>

Donate to the FNIH's Pandemic Response Fund to combat COVID-19:
fnih.org/pandemic

<image005.png>

From: Kim, Peter (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C48148E476824CE893260ACF33B0F774-KIMP2]
Sent: 8/13/2020 2:57:52 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Thanks Ashley! This is great news!

On Aug 12, 2020, at 11:24 PM, Adam, Stacey (FNIH) [T] [b6] wrote:

Thanks, Ashley,

We appreciate the follow-up. Thank you.

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 11:19 PM
To: Kim, Peter (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Hi Peter and Stacey,

Dropping everyone else off for the moment – not sure who really needs this info.

Please see the ACTIV-2 order schedule for the Abbott machines and tests below. The shipping POC, [b6] should receive the initial order of 17 machines and 15 kits (360 tests) by Monday, 8/17 and the remaining to follow each week. ADM Giroir's office also mentioned the POC will receive the tracking numbers, order confirmations, and may be contacted by Abbot for training/support if needed.

		12-Aug	16-Aug	23-Aug	30-Aug	6-Sep	13-Sep	20-Sep	T
Shipping Address	ACTIV-2 outpatient trial of monoclonal Ab								T
b6	Machines	17	15	13	10	0	0	0	5
	Kits	15	20	20	20	23	23	14	1

b6	Test	360	480	480	480	552	552	336	3

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, August 12, 2020 9:03 AM
To: Kim, Peter (NIH/NIAID) [E] b6; Javan, Arzhang (NIH/NIAID) [E]
b6; Adam, Stacey (FNIH) [T] b6; Judy Currier
b6; Davey Smith b6; Angie Greer
b6; BambraStokes b6; Lisa Oxtan
b6; Jackie Givens b6; Wong, Michelle (NIH/NIAID) [C]
b6; Jessica Holden b6; Erhardt, William (HHS/IOS)
b6
Cc: William Murtaugh b6; Grace Aldrovandi
b6; Alexis Sexton b6; Parker, CAPT Sheri
(HHS/IOS) b6; Church, Elizabeth (NIH/NIAID) [E] b6
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Hi Peter,

Thank you for confirming.

Best,
Ashley

From: Kim, Peter (NIH/NIAID) [E] b6
Sent: Wednesday, August 12, 2020 9:01 AM
To: Parker, Ashley (NIH/OD) [E] b6; Javan, Arzhang (NIH/NIAID) [E]
b6; Adam, Stacey (FNIH) [T] b6; Judy Currier
b6; Davey Smith b6; Angie Greer
b6; BambraStokes b6; Lisa Oxtan
b6; Jackie Givens b6; Wong, Michelle (NIH/NIAID) [C]
b6; Jessica Holden b6; Erhardt, William (HHS/IOS)
b6
Cc: William Murtaugh b6; Grace Aldrovandi
b6; Alexis Sexton b6; Parker, CAPT Sheri
(HHS/IOS) b6; Church, Elizabeth (NIH/NIAID) [E] b6
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Hi Ashley, all,

Thanks for the notice. I can confirm that the attached info is correct and that the machines and cartridges should be delivered to the distribution center below.

I'd like to note that it's extremely important that the [b6] info is listed prominently on the label.

b6

Thanks,
Peter

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 8:40 AM
To: Javan, Arzhang (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T]
[b6]; Judy Currier [b6]; Davey Smith
[b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Angie Greer
[b6]; BambraStokes [b6]; Lisa Oxtan
[b6]; Jackie Givens [b6]; Wong, Michelle (NIH/NIAID) [C]
[b6]; Jessica Holden [b6]; Erhardt, William (HHS/IOS)
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Hi Cyrus,

OWS has agreed to supply the attached number of machines and tests, however shipments will occur on a weekly basis until you have received the complete supply.

We only needed the addresses to ensure the supplies arrive at the correct location.

Thanks,
Ashley

From: Javan, Arzhang (NIH/NIAID) [E] [b6]
Sent: Wednesday, August 12, 2020 8:31 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6];
Judy Currier [b6]; Davey Smith [b6]; Kim, Peter
(NIH/NIAID) [E] [b6]; Angie Greer [b6]; BambraStokes
[b6]; Lisa Oxtan [b6]; Jackie Givens
[b6]; Wong, Michelle (NIH/NIAID) [C] [b6]; Jessica Holden
[b6]; Erhardt, William (HHS/IOS) [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Thanks Ashley. Yes this is likely where all supplies would likely be sent but Angie from PPD will have more real time information on the status of this list and our request for these important machines.

I will do my best to connect with the appropriate people before the deadline and provide an appropriate update by the requested time.

This will help ensure this important process is carried out efficiently and correctly.

Thanks.

Cyrus

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 8:23 AM
To: Javan, Arzhang (NIH/NIAID) [E] [b6]; Adam, Stacey (FNIH) [T]
[b6]; Judy Currier [b6]; Davey Smith
[b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Angie Greer
[b6]; BambraStokes [b6]; Lisa Oxtan
[b6] Jackie Givens [b6]; Wong, Michelle (NIH/NIAID) [C]
[b6]; Jessica Holden [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Below is the information we received for shipping. Is this address OK?

b6

Thank you,
Ashley

From: Javan, Arzhang (NIH/NIAID) [E] [b6]
Sent: Wednesday, August 12, 2020 8:19 AM
To: Adam, Stacey (FNIH) [T] [b6]; Judy Currier [b6]; Davey Smith
[b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Angie Greer
[b6]; BambraStokes [b6]; Lisa Oxtan
[b6] Jackie Givens [b6]; Wong, Michelle (NIH/NIAID) [C]
[b6]; Jessica Holden [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Thanks a lot Stacey.

I am copying in our PPD colleagues who have more granular details on this list of sites and the status of this list.

[b6] or anyone else from PPD, can you please review the request below and provide a status update.

Thanks a lot.

Best,
Cyrus

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 7:30 AM
To: Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines

Hi All,

Sorry for the duplicate emails, but I need to update the time we need these by. Could you please send them by 11am ET so Ashley will have time to compile with the others and have to OWS by noon.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Wednesday, August 12, 2020 7:26 AM
To: Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Javan, Arzhang (NIH/NIAID) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: VERY URGENT: Addresses for ACTIV-2 Sites to Receive Abbott Rapid Machines
Importance: High

Dear Judy, Davey, Peter, and Cyrus (since I know Peter is away),

Would it be possible for you to get me the addresses of the sites that you had wanted to receive the Abbott Machines for rapid testing?

Dr. Collins needs to send this to the OWS team by noon today if the machines are going to get shipped out this week.

I am cc'ing Ashley Parker who will help to get this list combined with those from the other NIH trials.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Direct: [b6] | Mobile: [b6]

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

<image001.jpg>

<image002.jpg>

<image003.jpg>

<image004.jpg>

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

<image005.png>

From: Rice, Todd [b6]
Sent: 7/27/2020 10:36:18 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Pulley, Jill [b6]; Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Yes – I did. Thank you, Dr. Parker.

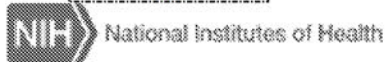
Todd

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 27, 2020 5:35 PM
To: Pulley, Jill [b6]; Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
Cc: Rice, Todd [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Received – you should have received a calendar invitation from Ayanna McManus.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



From: Pulley, Jill [b6]
Sent: Monday, July 27, 2020 4:07 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
Cc: Rice, Todd [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Ashley-
The additional PI is Dr. Todd Rice, copied.
Synopsis attached.
Excel file And back up slides will be sent momentarily.
Thanks,
-Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 27, 2020 2:36 PM
To: Pulley, Jill [b6]; Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Jill,

Thank you for confirming. Could you please send me the name and email of the additional PI and our team will be sending the invites shortly.

The single slide and completed excel file should be sufficient however feel free to submit a few additional back pocket slides is preferred.

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health

Tel: [b6]



National Institutes of Health

From: Pulley, Jill [b6]
Sent: Monday, July 27, 2020 2:59 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Jacobs, Chenoa [b6] Bernard, Gordon [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Ashley,
I will attend, Dr. Bernard will present. We also have another individual (Study PI) attending, would it be acceptable for us to forward the invite?
We will have our one slide summary to you shortly. Would a set of back up slides with further detailed information be helpful?
We will fill out the excel row ASAP in the file you provided.
Thank you so much! Looking forward to the call tomorrow.
Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 27, 2020 1:33 PM
To: Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
Cc: Pulley, Jill [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Chenoa and Dr. Gordon,

Thank you for confirming attendance for tomorrow's meeting. Will Jill plan to attend as well?

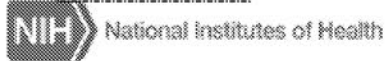
We are asking for one representative from each CP trial to present a single slide (5-min) with the requested details Dr. Collins provided below (to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results.

We are also collating this information into the attached spreadsheet if available.

Dr. Gordon are you interested in presenting a single slide and completing the information in the attached spreadsheet to be included for discussion tomorrow? If so, please send this information by **COB today** and we apologize for the quick turnaround.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



From: Jacobs, Chenoa <[b6]>
Sent: Monday, July 27, 2020 10:30 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Hello Ashley,
Dr. Gordon Bernard WILL be able to attend tomorrow's meeting.
Thanks,

Chenoa T. Jacobs
Executive Assistant to
Gordon R. Bernard, M.D.
Executive Vice President for Research
Director, Vanderbilt Institute for Clinical & Translational Research
Medical Center North, T-1208 | Nashville, TN 37232-2650

[b6]
[b6] - direct | 615.343-4479 - fax

VANDERBILT UNIVERSITY
MEDICAL CENTER

From: Pulley, Jill <[b6]>
Sent: Monday, July 27, 2020 7:50 AM
To: Bernard, Gordon <[b6]>
Cc: Jacobs, Chenoa <[b6]>
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Noting this
Please respond to Ashley Parker ([b6]) about your willingness to join the meeting.

Please respond

From: Bernard, Gordon <[b6]>
Sent: Monday, July 27, 2020 7:22 AM
To: Rice, Todd <[b6]>; Pulley, Jill <[b6]>; Self, Wesley H <[b6]>
Lindsell, Christopher John <[b6]>; Rhoads, Jillian P <[b6]>
Subject: Fwd: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Very interesting development!

Gordon Bernard sent from my iPhone

APAR0000006050

Begin forwarded message:

From: "Collins, Francis (NIH/OD) [E]" [b6] >

Date: July 27, 2020 at 5:54:08 AM CDT

To: [b6]

b6

b6

, Ralph Sacco

b6

Cc: "Parker, Ashley (NIH/OD) [E]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Fauci, Anthony (NIH/NIAID) [E]" [b6], "Gibbons, Gary (NIH/NHLBI) [E]" [b6], "Patterson, Amy (NIH/NHLBI) [E]" [b6], "Rutter, Joni (NIH/NCATS) [E]" [b6], "Kurilla, Michael (NIH/NCATS) [E]" [b6], "Woodcock, Janet (FDA/CDER)" [b6], "Disbrow, Gary (OS/ASPR/BARDA)" [b6], "Freire, Maria (FNIH) [T]" [b6], "Wholley, David (FNIH) [T]" [b6], "Marks, Peter (FDA/CBER)" [b6]

Subject: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Colleagues,

As the COVID-19 pandemic rages on in many parts of the world, it is absolutely urgent to obtain rigorous data on possible therapeutic interventions that could save lives. Convalescent plasma is one of the more promising interventions, but still lacks rigorous evidence from well-powered randomized controlled trials, though a number of such trials are underway. Janet Woodcock (who leads the therapeutics workstream for Operation Warp Speed) and I are interested in convening all of the groups engaged in such RCTs, to see if there might be a way to accelerate progress – both for individual trials that might be sped up, or by well-designed meta-analyses.

Considering the importance of the issue, convening this group for a real time conversation is urgent. Accordingly, I am inviting you to join a **90-minute virtual meeting tomorrow, Tuesday July 28, starting at 11 AM EDT**. Zoom links will be sent shortly.

I would like each group to come prepared to give a quick synopsis of the status of your trial efforts – to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results. In some instances (such as the C3PO study) I have invited more than one investigator working on a collaborative trial, and I would appreciate the PIs agreeing about who is the best position to summarize that trial.

I apologize in advance for the ridiculously short notice! But as in all things COVID, the usual timetables for organizing meetings have gone out the window.

Please respond to Ashley Parker [b6] about your willingness to join the meeting.

Many thanks, Francis

APAR0000006050

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health

[WARNING : This email came from an external source. Please treat this message with additional caution.]

[WARNING : This email came from an external source. Please treat this message with additional caution.]

[WARNING : This email came from an external source. Please treat this message with additional caution.]

[WARNING : This email came from an external source. Please treat this message with additional caution.]

From: Bernard, Gordon [b6]
Sent: 7/28/2020 8:03:46 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Pulley, Jill [b6]; Rice, Todd [b6]; Self, Wesley H [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Vanderbilt response
Attachments: 20200728_VUMC follow-up.pdf
Flag: Follow up

Dear Dr. Collins,

Thank you for convening investigators engaged in the study of convalescent plasma in Covid-19. Per your request at the end of the meeting today, please find attached our proposal for what we believe to be the fastest way to obtain the information needed to determine the safety and efficacy of convalescent plasma in the treatment of Covid-19.

Best
Gordon

Gordon R. Bernard M.D.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, July 27, 2020 5:54 AM
To: [b6] u;
[b6] Ralph Sacco
[b6]
Cc: [b6]
Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E]
[b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E]
[b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E]
[b6]; Rutter, Joni (NIH/NCATS) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E]
[b6]; Woodcock, Janet (FDA/CDER) [b6]; Disbrow, Gary
(OS/ASPR/BARDA) [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T]
[b6]; Marks, Peter (FDA/CBER) [b6]
Subject: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

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Please respond to Ashley Parker ([REDACTED] b6) about your willingness to join the meeting.

Many thanks, Francis

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health

[WARNING : This email came from an external source. Please treat this message with additional caution.]

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/25/2020 1:20:10 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: FW: Follow-up on OPV

Hi Francis, see below re: Bob Gallo OPV issue, as you requested.

From: Santos, Michael (FNIH) [T] [b6]
Sent: Tuesday, August 25, 2020 8:49 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: FW: Follow-up on OPV

Doug's email to Bob Gallo with the perspective of the Vaccines WG is below.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Lowy, Douglas (NIH/NCI) [E] [b6]
Sent: Tuesday, August 25, 2020 8:18 AM
To: Gallo, Robert [b6]
Cc: Santos, Michael (FNIH) [T] [b6]
Subject: Follow-up on OPV

Dear Bob,

Thanks for discussing with the ACTIV vaccine working group your proposal to evaluate live OPV for reducing the risk of COVID-19. The working group subsequently discussed this issue and were less enthusiastic about this potential intervention. They agreed there might be some interim utility from a heterologous vaccine, but thought the potential benefits from a specific vaccine were much greater and feasible, and should be the main focus of vaccine efforts against SARS-CoV-2. The group believes there is greater experimental support for the experimental use of BCG than OPV. There currently are several controlled trials of BCG that are exploring this question with SARS-CoV-2. In addition, there was some concern about possible harms from administering live OPV to at-risk adults. Although I recognize that this

perspective will be disappointing to you and your colleagues, we appreciated the opportunity to hear from you and to consider your proposal.

Best regards,
Doug

From: Fauci, Anthony (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DF38103D75134F658AE2D356F0396B94-AFAUCI]
Sent: 8/1/2020 1:24:56 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]
Subject: RE: Phone call with Dolsten (Pfizer)

Thanks, Francis. A phone call in two weeks would be a good idea.

Best regards,

Tony

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Saturday, August 1, 2020 9:10 AM
To: Fauci, Anthony (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Mascola, John (NIH/VRC) [E] [b6]
Subject: Phone call with Dolsten (Pfizer)

Hi all,

I've been remiss in not sending you a note sooner about the call I had with Mikael Dolsten a couple of days ago. This was a follow up to my suggestion that we might set up a plan for the chairs of the Pfizer DSMB and the NIH/OWS DSMB to communicate with each other about vaccine trials.

Bottom line – he won't go along with that. He's worried that having the Pfizer DSMB having access to unpublished information could represent a bias. They should be focused on published literature and the Pfizer trial results, nothing more. I tried to argue that the public would benefit from having this kind of cross comparison during the trials, but he wouldn't budge.

I learned a bit more about the Pfizer trial. It started last Monday. The "majority" of the sites are in the US, but he mentioned they might be planning to include Latin America (Brazil) in 2 weeks. Also thinking about Turkey and Germany.

He is very confident about their mRNA strategy, which is the full spike protein, not just the RBD. There are “some additional RNA modifications”. He says they got a nice CD8 Ag-specific response in the Phase 1 trial, as documented in their MedRxiv article (and notes that the Moderna vaccine did not result in CD8 activation). It’s a 30 ug dose, and in the primate challenge it prevented virus in the nose.

He would like to maintain informal communication with our trials. Maybe a phone meeting in two weeks with Fauci, Mascola, Lowy, Jensen? I said that would probably need to include Moderna, or it wouldn’t be balanced between the companies. I wonder if this is a virtual meeting that the ACTIV WG could convene?

He also wanted to share information about their IV protease inhibitor (I don’t have a name or number). So far just preclinical data, but they will start Phase I in late August. Another oral version is coming along soon. He wondered whether this agent could be a candidate for an October ACTIV trial (ACTIV-3) if the Phase I looks good.

That’s the current story. Having known and worked with Mikael for 10 years as part of AMP, I trust him to give straight answers – but I wish he was willing to be more interactive on the vaccine trials. No doubt he has other masters he has to answer to.

Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/28/2020 8:56:24 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: FW: Talking points for Francis at the Vaccines WG meeting

Francis, please see below for a few 'cues' for your discussion with the Vaccines WG tomorrow. David

From: Santos, Michael (FNIH) [T] [b6]
Sent: Tuesday, July 28, 2020 3:38 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Tolman, Brett <btolman@deloitte.com>
Subject: Talking points for Francis at the Vaccines WG meeting

Hi David,

We're looking forward to having Francis join us at tomorrow's Vaccines Working Group meeting.

Although the WG will continue working on two current topics (the implications of the first vaccine success and publication/dissemination of the vaccine-associated enhanced disease manuscript), this week does mark a transition for us to a demand-driven operating model. Going forward, we will gather the group together when there is a specified need and plan that the co-chairs are aligned on, rather than regularly calendaring meetings for either the main WG or the Sub-Groups.

Thus it is an opportune juncture to recognize some of the contributions of the Working Group and our three Sub-Groups:

- Discussions informing key aspects of the efficacy trials, including endpoints, populations, and success criteria
- Support for operationalization of trials, including epidemiological forecasting for site selection and input on the NIAID/CoVPN DSMB
- Planning for correlates of protection analyses, the potential lynchpin for approving multiple and improved vaccines after the initial success(es)
- Mapping the regulatory pathways for evaluation of vaccines for a scenario with insufficient (or slow) clinical endpoints
 - Unfortunately for the US, that contingency planning seems like it won't be necessary for the evaluation of the initial vaccine candidates, but may be part of corroborating correlates of protection
- Thoroughly assessing the evidence for enhanced disease in the context of COVID-19 vaccine development

We look forward to providing updates to ACTIV leadership at future meetings when we have a material update, and for ACTIV leadership to be in touch with the co-chairs to discuss potential priorities that they've identified.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
[b6] | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Stay at the forefront of FNIH news: fnih.org/newsletter

From: Clayton, Janine (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2453B3C2F90B40D1BAABC775DA03B5AD-CLAYTONJA]
Sent: 7/7/2020 1:38:51 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Corey MD, Larry [b6] Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lowy, Douglas (NIH/NCI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1b7b8fe4739478bb17840c56902718a-lowyd]; Nelson Michael [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c3323ab6a02468689fa2c51a87c43cc-NelsonMicha]; Perez-Stable, Eliseo (NIH/NIMHD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06f5c7aad094f6685d9f1d260d46441-perezstable]; Valantine, Hannah (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8b8263c5cc0442aaa0875846bd020e0-valantineh]; Wilson, Dave (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7525ed7759204341b78f96076898c011-wilsondr]; Gibbons, Gary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b71b953b50a5495ca0f2869ab13bc407-gibbonsgh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Denny, Joshua (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cdb4626dabbb45aa8b8e5d21169344e6-dennyjc]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]; Hooper, Monica (NIH/NIMHD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6d6c0a2a0304ca184b0c719bab8d080-hoopermw]; Parker, Karen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=22b34313c6374f7b96b645e80623a9cf-klparker]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]
Subject: RE: Vaccine trial recruitment
Attachments: Agenda and Actions Vaccine Trial Diversity_070420_JAC.docx

Hi Francis and colleagues,

In response to the call for potential outreach strategies for diversifying the participants in the vaccine trials, below is a list of potential approaches. To ensure the recruitment of diverse populations for these trials, tailored approaches to specific populations could be beneficial.

Pls

APAR0000006122

<https://orwh.od.nih.gov/toolkit/welcome/purpose>

NIH Inclusion Outreach Toolkit: How to Engage, Recruit, and Retain Women in Clinical Research

Designed to help PIs and research teams fulfill their responsibilities to include women in clinical research includes policies, case studies (including for Hispanic, and pregnant women) and recruitment and retention strategies. This could be expanded to include additional target populations and a COVID19-specific module.

General Public

- 1.) <https://www.fda.gov/consumers/womens-health-topics/diverse-women-clinical-trials-campaign-partners>
Diverse Women in Clinical Trials: FDA OWH and NIH ORWH partnered to create an outreach campaign and established partners that can be leveraged quickly to reach the public with ready to deploy materials and partner toolkits.
- 2.) In vetting ambassadors (or celebrities) for this initiative it might be advantageous to have multiple ambassadors for each group (AA, AI/AN, Latinx, pregnant women/children) to reach different demographics within the groups, such as by age, SES, gender, etc. I have listed other celebrities that might be of interest to think about vetting under each category. Also, well-respected thought leaders within specific communities may serve as great ambassadors (i.e. Johnetta B. Cole, the King family, etc.)
- 3.) Another strategy for outreach could be the use of customized advertisement of the studies via different media which will reach broad audiences.
 - a. Advertising the vaccine trials on radio shows that have targeted audiences. In addition, being hosted on a podcast where NIH scientist/clinician talks about the importance of the inclusion of diverse populations. In addition, ads on Spotify, Apple music, or Pandora could reach more audiences.
 - b. Ads about the trials can also be posted on online platforms, such as YouTube, Netflix, and Hulu.
 - c. Ads on Telemundo can be tailored for Latinx communities.

Institutions

- 1.) Connecting with presidents of minority serving institution to engage faculty, administrators, students, and communities around their respective schools is a viable strategy. NASEM is holding a webinar series on COVID and institutional responses that has featured several HBCU presidents (Spelman, Xavier, Virginia State) and will feature Hispanic Serving Institution presidents on July 8th.
- 2.) Also, connecting with faculty members who are highly-respected within communities, such as Dr. Lisa Cooper or Dr. Alondra Nelson can be useful.

Congress

- 1.) In addition, to the Congressional Black Caucus and the representatives you list on the document. We may want to add to the list Congresswomen Alma Adams and Lauren Underwood, who co-chair the Black Maternal Health Caucus, Congresswoman Robin Kelley, and the Women's Caucus.

Advocacy Groups and Societies

- 1.) Leveraging major professional societies is being considered. Many have formed community-based partnerships and developed awareness campaigns for targeted audiences. We could work with societies that have high impact, are already working on COVID-related issues, and have stakeholder/patient base disproportionately impacted by COVID (i.e. CA, heart disease, DM, etc.). Also, population health organizations can help with outreach strategies. (i.e. APHA, etc.)
- 2.) Civic organizations (e.g. Urban League), and Greek organizations (e.g. fraternities) can access large segments of particular demographic groups who can be mobilized for dissemination.

In the word document I also added a few suggestions for consideration. I'm happy to continue the conversation on this important effort.

Best,
Janine

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Sunday, July 5, 2020 2:18 PM
To: Fauci, Anthony (NIH/NIAID) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];
Wolinetz, Carrie (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6];
Lane, Cliff (NIH/NIAID) [E] [b6]; Mascola, John (NIH/VRC) [E] [b6]; Corey MD,
Larry [b6]; Wholley, David (FNIH) [T] [b6]; Lowy, Douglas (NIH/NCI) [E]
[b6]; Nelson Michael [b6]; Perez-Stable, Eliseo (NIH/NIMHD) [E]
[b6]; Valantine, Hannah (NIH/OD) [E] [b6]; Clayton, Janine (NIH/OD)
[E] [b6]; Wilson, Dave (NIH/OD) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E]
[b6]; Parker, Ashley (NIH/OD) [E] [b6]; Denny, Joshua (NIH/OD) [E]
[b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hooper, Monica (NIH/NIMHD) [E]
[b6]; Parker, Karen (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
Cc: McManus, Ayanna (NIH/OD) [E] [b6]
Subject: Vaccine trial recruitment

Dear colleagues,

Thanks for getting on the virtual call yesterday to discuss ways to optimize community outreach for the COVID-19 vaccine trials, beginning with the Moderna protocol. On the second page of the first attachment you will see the action items that I tried to capture from this very significant conversation. Please look closely at that list and comment on any errors of omission or commission, using the "reply all" for any that affect other parts of our group.

The second and third attachments are from Larry Corey, showing the location of recruitment sites for the Moderna trial. You will have seen the map from Larry yesterday, but also attached now is the list of specific recruitment sites (and zip codes) for the CROs that Moderna will be using. It will be particularly important for the leaders of NIMHD, NCATS, NHLBI, and *All of Us* to identify ways to link up with the existing recruitment plans. In that regard, I would like to reconvene that group of leaders this coming week to see what more might be done to activate the community outreach efforts in the areas where recruitment will be getting underway.

I also attach a message from Hannah Valantine, who was unable to log on to the Zoom call but had a few thoughts to share.

Thanks for your help on this – it really matters that we do everything possible to get this right.

Best, Francis

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 7/22/2020 9:14:42 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
Subject: Re: STAT Article on Vaccine Distribution

Thanks, Ashley. Yes, we saw it.

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health

b6

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Wednesday, July 22, 2020 1:23:25 PM
To: Myles, Renate (NIH/OD) [E] b6 Burklow, John (NIH/OD) [E] b6
Subject: FYI: STAT Article on Vaccine Distribution

FYI – Francis has already received the STAT article below from FNIH and OCPL may have seen this already but sharing just in case.

From: Menetski, Joseph (FNIH) [T] b6
Sent: Wednesday, July 22, 2020 8:04 AM
To: Wholley, David (FNIH) [T] b6; Collins, Francis (NIH/OD) [E] b6 Tabak, Lawrence (NIH/OD) [E] b6 Freire, Maria (FNIH) [T] b6 Lane, Cliff (NIH/NIAID) [E] b6; Parker, Ashley (NIH/OD) [E] b6 Anderson, James (NIH/OD) [E] b6 Austin, Christopher (NIH/NCATS) [E] b6
Subject: RE: ACTIV Daily Update July 22

Vaccine distribution

https://www.statnews.com/2020/07/22/confusion-spreads-over-system-to-determine-priority-access-to-covid-19-vaccines/?utm_source=STAT+Newsletters&utm_campaign=21ebd8b91a-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-21ebd8b91a-149573977

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 7/21/2020 1:20:29 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Fennington, Kelly (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e2d306aa244429b0f51d365bd24a26-fenningk]
Subject: RE: NAM Committee on Vaccine Distribution

Cool! - I thought so. Beth Bell who presented to the Vaccine WG was unaware and I suppose she'll find out in due time.

From: Wolinetz, Carrie (NIH/OD) [E] [b6]
Sent: Tuesday, July 21, 2020 9:04 AM
To: Parker, Ashley (NIH/OD) [E] [b6] Culp, Michelle (NIH/OD) [E] [b6]
Fennington, Kelly (NIH/OD) [E] [b6]
Subject: RE: NAM Committee on Vaccine Distribution

ACIP is looped in to this effort, it was carefully negotiated with CDC with ACIP specifically in mind. FNIH is just out of the loop.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, July 21, 2020 8:59 AM
To: Culp, Michelle (NIH/OD) [E] [b6] Fennington, Kelly (NIH/OD) [E] [b6]
Cc: Wolinetz, Carrie (NIH/OD) [E] [b6]
Subject: RE: NAM Committee on Vaccine Distribution

Thanks, Michelle. Looping in Carrie as FYI – there is a NASEM vaccine summit on Thursday, FC is slated to give remarks and this could be useful background.

Thanks again,
Ashley

From: Culp, Michelle (NIH/OD) [E] [b6]
Sent: Tuesday, July 21, 2020 7:26 AM
To: Parker, Ashley (NIH/OD) [E] [b6] Fennington, Kelly (NIH/OD) [E] [b6]
Subject: FW: NAM Committee on Vaccine Distribution

Dear Kelly and Ashely,
In case you and others are interested in the hub bub....The ACIP gave a presentation to the ACTIV Vaccine WG last week. See comments below from FNIH regarding the NAM Vaccine Distribution Framework committee composition. I understand there are issues NAM must consider that others would not be aware of.

Best,
Michelle

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Tuesday, July 21, 2020 7:15 AM
To: Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Melencio, Cheryl

(FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T]
[b6]
Cc: Culp, Michelle (NIH/OD) [E] [b6]
Subject: RE: NAM Committee on Vaccine Distribution

You will notice, this is co-sponsored but NIH AND CDC. Even more interesting why ACIP didn't have a line on this?

From: Santos, Michael (FNIH) [T] [b6]
Sent: Tuesday, July 21, 2020 12:49 AM
To: Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T]
[b6]
Cc: Culp, Michelle (NIH/OD) [E] [b6]
Subject: RE: NAM Committee on Vaccine Distribution

Hi Joe,

Great, thanks for sharing.

Many of their proposed topics are topics that ACIP is already working on, so they should probably reach out as soon as they're constituted to understand how to work with them during their process (given that informing ACIP is a stated goal): if they wait for their report 4 months from now it will probably be too late.

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Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Monday, July 20, 2020 8:57 PM
To: Adam, Stacey (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T]
[b6]
Subject: FW: NAM Committee on Vaccine Distribution

FYI

Subject: RE: NAM Committee on Vaccine Distribution

"Tis: <https://www8.nationalacademies.org/pa/projectview.aspx?key=52173>

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/1/2020 10:40:01 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: Re: NEJM Perspective CHIMs

Ok will do

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From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, July 1, 2020 6:13:00 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Santos, Michael (FNIH) [T] [b6]
Subject: NEJM Perspective CHIMs

Cheryl, can you please send this out tonight under my name? Should go to all on the meeting roster today. Thanks

Dear ACTIV Leadership Team and meeting participants,

As discussed on our ACTIV Leadership Team call this afternoon, please see attached the just released *NEJM Perspective on Accelerating Development of SARS-CoV-2 Vaccines — The Role for Controlled Human Infection Models*, authored by members of the ACTIV Vaccines Working Group.

Congratulations to the Vaccines WG members who've worked hard on this publication and to all the support from the Leadership Group on their efforts!

Thanks,
David Wholley

From: Fennington, Kelly (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C3E2D306AA244429B0F51D365BD24A26-FENNINGK]
Sent: 7/21/2020 11:58:35 AM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: NAM Committee on Vaccine Distribution

This is really helpful Michelle, thanks for sharing with us.

Kelly

From: Culp, Michelle (NIH/OD) [E] [b6]
Sent: Tuesday, July 21, 2020 7:26 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Fennington, Kelly (NIH/OD) [E] [b6]
Subject: FW: NAM Committee on Vaccine Distribution

Dear Kelly and Ashely,

In case you and others are interested in the hub bub....The ACIP gave a presentation to the ACTIV Vaccine WG last week. See comments below from FNIH regarding the NAM Vaccine Distribution Framework committee composition. I understand there are issues NAM must consider that others would not be aware of.

Best,
Michelle

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Tuesday, July 21, 2020 7:15 AM
To: Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Culp, Michelle (NIH/OD) [E] [b6]
Subject: RE: NAM Committee on Vaccine Distribution

You will notice, this is co-sponsored but NIH AND CDC. Even more interesting why ACIP didn't have a line on this?

From: Santos, Michael (FNIH) [T] [b6]
Sent: Tuesday, July 21, 2020 12:49 AM
To: Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Culp, Michelle (NIH/OD) [E] [b6]
Subject: RE: NAM Committee on Vaccine Distribution

Hi Joe,

Great, thanks for sharing.

Many of their proposed topics are topics that ACIP is already working on, so they should probably reach out as soon as they're constituted to understand how to work with them during their process (given that informing ACIP is a stated goal); if they wait for their report 4 months from now it will probably be too late.

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Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Menetski, Joseph (FNIH) [T] [b6]

Sent: Monday, July 20, 2020 8:57 PM

To: Adam, Stacey (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]

Subject: FW: NAM Committee on Vaccine Distribution

FYI

Subject: RE: NAM Committee on Vaccine Distribution

"Tis: <https://www8.nationalacademies.org/pa/projectview.aspx?key=52173>

From: Culp, Michelle (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E38FA37E0424217AA0A283CBA9E5098-MCULP]
Sent: 7/22/2020 5:10:30 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: RE: ACTIV Daily Update July 22

Thanks for sharing – interesting!

The article mentions Lt. Gen. Paul Ostrowski from OWS. He presented to the ACTIV Vaccine subgroup on Friday, after Beth Bell. He definitely exudes a sense of control and order.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, July 22, 2020 12:23 PM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]
Subject: FW: ACTIV Daily Update July 22

FYI

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Wednesday, July 22, 2020 8:04 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Subject: RE: ACTIV Daily Update July 22

Vaccine distribution

https://www.statnews.com/2020/07/22/confusion-spreads-over-system-to-determine-priority-access-to-covid-19-vaccines/?utm_source=STAT+Newsletters&utm_campaign=21ebd8b91a-MR_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-21ebd8b91a-149573977

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/13/2020 9:56:33 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]
Subject: RE: ACTIV Trial Recruitment - Community Engagement

Perfect, thank you Ashley!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 13, 2020 5:44 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>
Subject: RE: ACTIV Trial Recruitment - Community Engagement

Hi David,

Attached is a slide summarizing the CT enrollment discussions and next steps/immediate actions.

Best,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, July 13, 2020 3:28 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>
Subject: RE: ACTIV Trial Recruitment - Community Engagement

Hi David,

Not a problem – I will send something by COE.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, July 13, 2020 2:50 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>
Subject: ACTIV Trial Recruitment - Community Engagement

Hi Ashley,

We have put a slide into the ACTIV EC deck for Wednesday's call with the above title as a placeholder, because I think Francis will want to give the group an update on what has happened in this area since it was discussed on the Leadership Team call July 1. I know that this morning Francis mentioned the conversations with OWS, with the Moderna leadership, and with NIH Leadership, resulting in the formation of some kind of plan that Gary Gibbons and someone whose name I did not catch are responsible for putting together, and which we will subsequently review with the ACTIV 1-4 Study Teams. But I don't have any of the details about what was done, who met with whom, etc, and what the plan is that

Francis wants to articulate. I was wondering if you could briefly outline this on a simple strawman slide that we can refine into something more finished to show Francis tomorrow at 1:45 when we do our pre-call. If you can provide 5 or so bullets, our Deloitte colleagues can do whatever is needed to format it into an appropriate slide. Would this be possible? Thanks

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Gonzalez, Nina [ningonzalez@deloitte.com]
Sent: 7/13/2020 9:46:36 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]
Subject: RE: ACTIV Trial Recruitment - Community Engagement

Hi Ashley,

Thank you kindly, we will add this to our deck for review.

Also, stay tuned, Olivia will be sharing the updated roster slide for your review shortly.

Thank you!

Nina Gonzalez

Get Outlook for iOS

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 13, 2020 5:43:57 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>
Subject: [EXT] RE: ACTIV Trial Recruitment - Community Engagement

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Sent: Monday, July 13, 2020 3:28 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>
Subject: RE: ACTIV Trial Recruitment - Community Engagement

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From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, July 13, 2020 2:50 PM
To: Parker, Ashley (NIH/OD) [E] [b6]

Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>

Subject: ACTIV Trial Recruitment - Community Engagement

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David Wholley

Senior Vice-President, Research Partnerships

Foundation for the National Institutes of Health

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 6/29/2020 5:14:53 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: NEJM accepted the CHIM manuscript today

Great!

Thanks for letting me know.

Francis

From: Santos, Michael (FNIH) [T] [b6]
Sent: Monday, June 29, 2020 12:44 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: NEJM accepted the CHIM manuscript today

Hi Francis,

I wanted to provide an update on the controlled human infection model paper from the ACTIV Vaccines Working Group: NEJM accepted the paper this morning. We will let you know once the timeline for publication is clear.

Thank you for engaging to support this.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
[b6] | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Stay at the forefront of FNIH news: fnih.org/newsletter

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/18/2020 4:36:37 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: FW: Public campaign for vaccine trial enrollment

Resending this to all.

From: Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [b6]
Sent: Wednesday, June 17, 2020 2:08 PM
To: Mascola, John (NIH/VRC) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Public campaign for vaccine trial enrollment

Francis and Tony:

We have been working across the Interagency and with the CoVPN in the last few weeks to execute a landscape review of both Community Engagement and Strategic Communication capabilities and capability gaps. We will unveil a Strategic Plan for same on an ACTIV call this Friday 1200-1300 EDT led by one of the CoVPN Co-Chairs, Dr. Larry Corey, and myself representing OWS/Vaccine Development Team (John Mascola, Chair).

The CoVPN has had an extensive and robust community engagement and outreach program to the young black and LatinX populations for over a decade including a program with black church leaders. This has resulted in the ability to enroll these populations into their HIV vaccine trials quite successfully. Thus, leveraging this expertise and expanding it into COVID-19 at-risk populations has been the immediate goal.

This expansion plan has been implemented quickly, first by email over the last week and then a lively VTC at 1200 EDT hrs today. This has involved an expanding group of experts in community engagement, vaccine/medical countermeasure development, communications, and vaccine implementation campaigns. Critically, while built around a core of HIV experienced professionals, the current group is much more representative of respiratory disease vaccine experts who touch a larger range of at-risk populations. Representatives are included from NIAID (OD, VRC, DAIDS, DMID), CDC, BARDA, DOD, and DA (Dept of the Army). We have been in constant contact with newer stakeholders inclusive of geriatric, industry, faith based, Native/Pacific Islander, LatinX, and black communities to ensure an optimal balance of cultural competencies. Our BARDA colleagues will facilitate interoperability with the community engagement activities centered at the NIAID supported CoVPN sites to the industry sponsored CROs that will represent approximately 50% of clinical trial sites in the upcoming OWS vaccine phase 3 trials.

Ultimately, our community engagement and communication efforts supporting vaccine phase 3 trials need to lead up to those of CDC who will be charged with the stewardship of vaccine implementation campaigns. Thus, it is critical that CDC is working with us from the beginning of the life cycles of our medical countermeasure development processes.

We hope to have mature presentation products by COB on Thursday, 18 July, that we will hand up to senior NIH leaders prior to the Friday ACTIV call.

Pending your questions and guidance,

Nelson Michael

Nelson L. Michael, M.D., Ph.D.
Department of the Army Civilian
Director, Center for Infectious Diseases Research
Walter Reed Army Institute of Research
503 Robert Grant Avenue
Silver Spring, MD 20910
Office: [REDACTED]
Mobile: [REDACTED]
Email: [REDACTED]
Email: [REDACTED]

From: Mascola, John (NIH/VRC) [E] [REDACTED]
Sent: Wednesday, June 17, 2020 10:56 AM
To: Fauci, Anthony (NIH/NIAID) [E] [REDACTED]; Collins, Francis (NIH/OD) [E] [REDACTED]; Tabak, Lawrence (NIH/OD) [E] [REDACTED]; Wolinetz, Carrie (NIH/OD) [E] [REDACTED]; Burklow, John (NIH/OD) [E] [REDACTED]; Myles, Renate (NIH/OD) [E] [REDACTED]; Wholley, David (FNIH) [T] [REDACTED]; Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) [REDACTED]
Subject: [Non-DoD Source] RE: Public campaign for vaccine trial enrollment

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Francis, Tony,

I will ask Nelson Michael, who is on our OWS vaccine team and is DoD colleague from Walter Reed, to give you an email update on some ongoing and planned community engagement activities in context of phase 3 trials. He and others are also briefing ACTIV on this topic soon.

Nelson – please comment here.

Thanks,
John

From: Fauci, Anthony (NIH/NIAID) [E] [REDACTED]
Sent: Wednesday, June 17, 2020 7:20 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED]; Tabak, Lawrence (NIH/OD) [E] [REDACTED]; Wolinetz, Carrie (NIH/OD) [E] [REDACTED]; Burklow, John (NIH/OD) [E] [REDACTED]; Myles,

Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Mascola, John (NIH/VRC)

[E] [b6]

Subject: RE: Public campaign for vaccine trial enrollment

Francis et al:

Agree with your plan. Also, Michael Caputo (new ASPA at HHS) has actually been thinking about the same thing and was hoping to use PSAs and Instagram tools with celebrities, including Rap Groups with whom I have already engaged, as you have suggested. We should probably at least let him know what we are doing and get some Department buy in and help. Also, we should get the CDC to partner with us since this is part of their mandate. Look forward to further discussion and action.

Best,

Tony

Anthony S. Fauci, MD

Director

National Institute of Allergy and Infectious Diseases

Building 31, Room 7A-03

31 Center Drive, MSC 2520

National Institutes of Health

Bethesda, MD 20892-2520

Phone: [b6]

FAX: (301) 496-4409

E-mail: [b6]

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From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Wednesday, June 17, 2020 6:54 AM

To: Tabak, Lawrence (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E]

[b6]; Myles, Renate (NIH/OD) [E]
[b6]; Wholley, David (FNIH) [T]

[b6]; Mascola, John (NIH/VRC) [E]
[b6]; Fauci, Anthony (NIH/NIAID) [E]

Subject: Public campaign for vaccine trial enrollment

Hi Larry, Carrie, John B, Renate, David, John M, and Tony,

I spoke with Moncef last night about other things, and raised the issue with him about preparing for a massive campaign to enroll as many as 150,000 participants (30,000 for each vaccine) in the vaccine trials that will start in about three weeks. The enrollment will be regional (depending on where the virus is actively spreading) and will need to reach out to a wide demographic, not just healthy 20- or 30-something college grads. We will particularly want to know whether the vaccine prevents serious illness in those at highest risk.

APAR0000006170

As far as I can tell, there is not yet an organized plan about how to do this outreach – though it's possible that the companies involved (or their CROs) have already got something going. But this seems like a moment to pull in ideas and resources. I would think this would be a great time to enlist the help of celebrities (Tom Hanks, Steph Curry) and trusted doctors (Tony Fauci, Jerome Adams, Reed Tuckson, maybe even, gulp, Dr. Oz). Shouldn't we be putting together a draft campaign right now, that could be slotted into the regions where recruitment is needed?

I'd be interested in your thoughts on this. Then maybe we should pull a group together?

Francis

From: Lane, Cliff (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2D7E368A3137473BBCE161547A82F2DE-CLANE]
Sent: 5/23/2020 10:59:08 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: Follow-up on establishing the DSMB for the Vaccines harmonized MP

Happy to take care of the first part.

From: "Wholley, David (FNIH) [T]" [b6]
Date: Saturday, May 23, 2020 at 6:57 PM
To: "Lane, Cliff (NIH/NIAID) [E]" [b6], "Collins, Francis (NIH/OD) [E]" [b6], Lawrence Tabak [b6], "Freire, Maria (FNIH) [T]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: RE: Follow-up on establishing the DSMB for the Vaccines harmonized MP

Sure, as long as there is clear endorsement from NIAID and clear direction to the Vaccines WG from leadership to do exactly that.

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Saturday, May 23, 2020 6:24 PM
To: Wholley, David (FNIH) [T] [b6], Collins, Francis (NIH/OD) [E] [b6], Tabak, Lawrence (NIH/OD) [E] [b6], Freire, Maria (FNIH) [T] [b6], Austin, Christopher (NIH/NCATS) [E] [b6], Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Follow-up on establishing the DSMB for the Vaccines harmonized MP

I think the goal should be to have a single DSMB to review the vaccine efficacy trials supported by the federal government. That will insure some consistency in the reporting and review of blinded data. For that to be the case, the membership of the DSMB and the charter of the DSMB should be endorsed (at a minimum) by ACTIV. Similar comments would apply to therapeutics.

I am happy to ask NIAID to put together a proposed membership and proposed charter to be reviewed and endorsed by ACTIV. I did not mean to imply that the ACTIV vaccine group would do the work of setting up the DSMB, rather that they would be engaged and endorse the concept, make-up and charter. There are some subtle points here that will require agreement from industry and government that are best worked out prior to any protocol being finalized.

Cliff

From: "Wholley, David (FNIH) [T]" [b6]
Date: Saturday, May 23, 2020 at 1:06 PM
To: "Lane, Cliff (NIH/NIAID) [E]" [b6], "Collins, Francis (NIH/OD) [E]" [b6],

Lawrence Tabak <[REDACTED] b6> "Freire, Maria (FNIH) [T]" <[REDACTED] b6> "Austin, Christopher (NIH/NCATS) [E]" <[REDACTED] b6> "Parker, Ashley (NIH/OD) [E]" <[REDACTED] b6>

Subject: Follow-up on establishing the DSMB for the Vaccines harmonized MP

As promised I followed up with Mike Santos. Mike reminded me that when we had the discussion with the ACTIV Vaccines WG co-chairs about master protocol design several Sundays ago we made it clear (based on the previous day's conversation with Tony Fauci and Peter Marks) that NIAID was going to move forward with a harmonized MP based on an initial protocol to include Moderna and ChAdOx1 vaccines, and that the plan was that all studies funded by the government (i.e., BARDA-funded) would be mandated to use a single DSMB. The Working Group was to contribute some potential names, and that was it—they were otherwise taking a step back from the actual protocol design. Mike said that suggestions for names of DSMB members were being sent to Doug Lowy by the WG members; he is not sure of how many have been suggested but will check.

If, as I think Cliff suggested today, there is now an expectation that the WG will do more than suggest names—e.g., put the group together, make invitations, set a charter and set up meetings—then I think that will require a new and different directive from the ACTIV leadership to do so. And given what I understand his position to be on the org chart from today's call, I think we'd want to make sure John Mascola is in complete agreement with that approach.

David

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

([REDACTED] b6)

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11400 Rockville Pike Suite 600 North Bethesda, MD 20852

In 2019, the FNIH earned the highest rating from Charity Navigator for the fifth consecutive year and was recognized as an organization that exceeds industry standards.

From: Anderson, James (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=73143D1860BC42458BE254CA21573B23-ANDERSONJM]
Sent: 5/19/2020 12:16:13 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: FOR REVIEW: Draft manuscript on SARS-CoV-2 controlled human infection model

I agree with all comments and have nothing to add.
Jim

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Tuesday, May 19, 2020 8:12 AM
To: Lane, Cliff (NIH/NIAID) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Santos, Michael (FNIH) [T] [b6]
Subject: Re: FOR REVIEW: Draft manuscript on SARS-CoV-2 controlled human infection model

Not much to add other than to ask if there a clear path to add ethics consult/discussion to this mix?
Larry

From: "Lane, Cliff (NIH/NIAID) [E]" [b6]
Date: Tuesday, May 19, 2020 at 8:03 AM
To: Francis Collins [b6]; "Wholley, David (FNIH) [T]" [b6]; "Freire, Maria (FNIH) [T]" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]; "Austin, Christopher (NIH/NCATS) [E]" [b6]; "Parker, Ashley (NIH/OD) [E]" [b6]; "Anderson, James (NIH/OD) [E]" [b6]
Cc: "Santos, Michael (FNIH) [T]" [b6]
Subject: Re: FOR REVIEW: Draft manuscript on SARS-CoV-2 controlled human infection model

I think the primary argument is that we need the quickest path to a safe and effective vaccine. In the absence of an ability to rapidly launch the appropriate randomized, clinical trials (which will give appropriate efficacy AND safety data) controlled human challenge studies should be considered – with all the caveats (with additional emphasis on the ethics). At present, with a global pandemic, that is not the case for COVID-19. I think there should be some discussion of how this fits into a regulatory pathway with an ultimate goal of approval (not just EUA). I also think if this is going to be branded as an ACTIV work product it should follow a (to be determined) process. In this instance, some review and approval/endorsement by the entire vaccine group (including FDA and industry reps).

Cliff

From: "Collins, Francis (NIH/OD) [E]" <[REDACTED]>
Date: Tuesday, May 19, 2020 at 6:55 AM
To: "Wholley, David (FNIH) [T]" <[REDACTED]> "Freire, Maria (FNIH) [T]" <[REDACTED]>, Lawrence Tabak <[REDACTED]> "Austin, Christopher (NIH/NCATS) [E]" <[REDACTED]>, "Lane, Cliff (NIH/NIAID) [E]" <[REDACTED]> "Parker, Ashley (NIH/OD) [E]" <[REDACTED]> "Anderson, James (NIH/OD) [E]" <[REDACTED]>
Cc: "Santos, Michael (FNIH) [T]" <[REDACTED]>
Subject: FW: FOR REVIEW: Draft manuscript on SARS-CoV-2 controlled human infection model

Hi there War Room team,

I've had a chance to read through the manuscript from the Vaccines WG on human challenge trials (which they refer to as CHIMs, controlled human infection models). They present some very practical challenges that would make it difficult to mount such a project and expect results in less than 1 – 2 years. That's a useful counter-perspective to some proposals I have heard (including from Debbie Birx) that suggest this could be all done by September.

But I have major concerns about the manuscript in its current form:

b5

I'm curious to know what the rest of you think.

Francis

From: Santos, Michael (FNIH) [T] <[REDACTED]>
Sent: Monday, May 18, 2020 8:19 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED]> Marks, Peter (FDA/CBER) <[REDACTED]>
Cc: Parker, Ashley (NIH/OD) [E] <[REDACTED]>; Wholley, David (FNIH) [T] <[REDACTED]>; Kathleen Neuzil <[REDACTED]> Michael, Nelson L CIV USARMY MEDCOM WRAIR (USA) <[REDACTED]> Cohen, Myron <[REDACTED]>; Robb, Merlin <[REDACTED]> Tolman, Brett <btolman@deloitte.com>
Subject: FOR REVIEW: Draft manuscript on SARS-CoV-2 controlled human infection model

APAR0000006200

Hi Francis and Peter,

Per your charge to the Vaccines Working Group, a small team was formed to articulate the scientific and practical requirements of implementing SARS-CoV-2 human challenge studies, with the intent that this would be a useful complement to the numerous ethical analyses. After consultations with prominent proponents of the idea and discussion within the Working Group, they developed the attached draft manuscript and figure, which conclude that the development of a controlled human infection model is expected to take 1-2 years, longer than the expected timeline for phase 3 trials to identify efficacious vaccines.

We would appreciate your review and input, and would be happy to set up a time to discuss if that would be helpful.

Best regards,
Mike

Michael Santos, PhD
Associate Vice President, Science
Foundation for the National Institutes of Health
b6 fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 5/16/2020 3:19:31 PM
To: Adams, Peter (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f6e22f801f9146ef90116c4311c6f3ee-Peter.Adams]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Annaliesa [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; Carter, Kara [b6]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Cihlar, Tomas [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Deming, Damon (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a5ace9923ae415aa3d85ac09cb76f85-DEMINGD.fda]; Diamond, Michael [b6]; Duncan, Ken [b6]; Fernandes, Prabhavathi [b6]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Gatto, Greg [b6]; Grobler, Jay [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Lutz, Cat [b6]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskiJP]; Nestle, Frank [b6]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Payne, David [b6]; Pitt, Louise [b6]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Qashu, Felicia (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=366447a553f44696b2c79484d90e41e5-qashufm]; Rao, Srinivas [b6]; Rappaport, Jay [b6]; Stegmeier, Frank [b6]; Young, John [b6]
Subject: FW: Questionnaire -

Dear WG,

Please see the links below forwarded from Hilary Marston (NIAID). As she suggests, distribute as you see appropriate.

Joe

From: Marston, Hilary (NIH/NIAID) [E] [b6]
Sent: Friday, May 15, 2020 3:54 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Dominique, Joyelle (NIH/NIAID) [E] [b6]; Handley, Gray (NIH/NIAID) [E] [b6]
Subject: FW: Questionnaire -

David -

A number of staff at NIAID received these requests for information from WHO. While we are trying to be responsive to WHO in an effort to continue technical engagement, we also understand that much of this information is already being collected under other initiatives, including ACTIV.

The first survey is related to expressing interest in the WHO Solidarity vaccine trial. We've already informed WHO that we cannot propose clinical sites for their vaccine trial, as our sites are autonomous and will need to determine which trials that they will participate in (though NIAID funding will go to support our trials, and likely would not be available for Solidarity site support).

The second survey is requesting information on laboratory animal capacity. We think this may be information that NIH could share. I am of course aware that ACTIV the preclinical WG has collected similar information. Given this, would it be more efficient to direct that portion to FNIH for response?

Many thanks for considering,

Hilary

From: "GSELL, Pierre" [b6]
Date: Sunday, May 10, 2020 at 5:21 AM
Subject: Questionnaire -

Dear all,

We are pleased to invite you to answer to the 2 following call for interests -

- Call for interest in engagement of vaccine trial sites in evaluation of COVID19 vaccines in adaptive multi-country global Solidarity Vaccine Trial - <https://www.who.int/news-room/articles-detail/call-for-interest-in-engagement-of-vaccine-trial-sites-in-evaluation-of-covid19-vaccines-in-adaptive-multi-country-global-solidarity-vaccine-trial>
Access to survey - <https://enketo.lshtm.ac.uk/:5qVzS2ez>
- Mapping animal lab capacity to accelerate COVID-19 vaccine and therapeutic development
Access to survey - <https://enketo.lshtm.ac.uk/:SVcm9oTW>

Please disseminate the links extensively.

Kind regards.

Pierre on behalf of the R&D Blueprint team.

From: GSELL, Pierre
Sent: 26 March 2020 10:44
Subject: RE: COVID-19 – GCM/SAG TC - Thursday 26 March - 12pm Geneva time

KIND REMINDER, call in about 1 hour + attaching global call codes

Dear all,

We are pleased to invite you to a follow-up 1 hour TC on COVID-19 research activities.

Agenda items:

- Update on the progress in the Forum Research and Innovation thematic areas (WHO focal points and/or chairs)
- Update on research activities from partners

Dial-in details:

Thursday 26 March – 12pm Geneva time

b6 / Participant d **b6**

Kind regards

Pierre on behalf of Blueprint team

From: Minnich, Beth [b6]
Sent: 5/13/2020 10:15:27 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Corey MD, Larry [b6]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: Time Sensitive Request for Dr. Collins | Vaccine Slides Presented to Vaccine WG
Attachments: activ vaccine subcommitte clinical endpoints discussion slides for distribution_final.pptx

Hi Ashley,

In follow up to the below, please see the attached.

Best wishes,

Beth

From: Minnich, Beth
Sent: Wednesday, May 13, 2020 2:56 PM
To: [b6]
Subject: RE: Time Sensitive Request for Dr. Collins | Vaccine Slides Presented to Vaccine WG

Hi Ashley,

I'll be sending you the slides very shortly.

Best wishes,

Beth Minnich
Executive Assistant to Dr. Larry Corey

From: Corey MD, Larry [b6]
Sent: Wednesday, May 13, 2020 2:39 PM
To: Minnich, Beth [b6]
Subject: FW: Time Sensitive Request for Dr. Collins | Vaccine Slides Presented to Vaccine WG

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 12:10 PM
To: Corey MD, Larry [b6]; Gilbert PhD, Peter B [b6]
Cc: Santos, Michael (FNIH) [T] [b6]; Tolman, Brett [b6]; Wholley, David (FNIH) [T]
[b6]
Subject: Time Sensitive Request for Dr. Collins | Vaccine Slides Presented to Vaccine WG

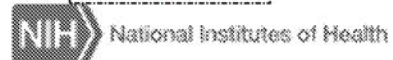
Good afternoon Larry and Peter,

Dr. Collins has a meeting tomorrow morning with the NIH institute directors and would like to give them an update on the proposed harmonized protocol for vaccines. Can we please have a copy of the slides presented today as soon as possible?

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health

Tel: b6



From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/7/2020 8:21:29 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: Vaccine master protocol discussion on ACTIV LT meeting yesterday

Dear All,

I followed up with Mike Santos immediately following our call today regarding the issue of vaccine trial design. There has indeed been discussion, and some strong sentiment from committee members (notably Larry Corey), about the operational complexity of a single trial design and the risk it poses to feasibility.

The committee discussions have also advanced the view that there may well be sufficient value in protocol standardization and sharing of data so that having a single master protocol adaptive platform trial may not be entirely necessary if it proves too risky.

But the discussion in the committee was not conclusive: the actual detailed protocol design discussions have yet to take place, and no formal vote has been taken on the issue. Mike was himself a little surprised at to hear the separate trial view endorsed on the call yesterday so strongly. Look forward to hearing the result of NIAID's discussions on this.

David

From: Marovich, Mary (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BFD0192D165D4643ACCF6347728DBAEB-MAROVICHMA]
Sent: 5/5/2020 5:35:48 PM
To: Cohen, Myron [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]; Corey MD, Larry [b6]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Mascola, John (NIH/VRC) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f78b40a596b4ca4a2850a429d1ae3f2-jmascola]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tolman, Brett [btolman@deloitte.com]
Subject: RE: ACTIV and antibodies

Vir, AZ and AbCellera/Lilly have expressed interested in "basket" studies in different clinical testing situations.

From: Cohen, Myron S [b6]
Sent: Tuesday, May 5, 2020 1:21 PM
To: Corey MD, Larry [b6]; Santos, Michael (FNIH) [T] [b6]
Cc: Mascola, John (NIH/VRC) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Marovich, Mary (NIH/NIAID) [E] [b6]; Tolman, Brett <btolman@deloitte.com>
Subject: RE: ACTIV and antibodies

AZ for sure

From: Corey MD, Larry [b6]
Sent: Tuesday, May 5, 2020 1:08 PM
To: Cohen, Myron S [b6]; Santos, Michael (FNIH) [T] [b6]
Cc: Mascola, John (NIH/VRC) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Marovich, Mary (NIH/NIAID) [E] [b6]; Tolman, Brett <btolman@deloitte.com>
Subject: RE: ACTIV and antibodies

I think they would be a helpful addition ; are their other companies you think might be interested?

From: Cohen, Myron S [b6]
Sent: Tuesday, May 5, 2020 6:45 AM
To: Santos, Michael (FNIH) [T] [b6]
Cc: Mascola, John (NIH/VRC) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Marovich, Mary (NIH/NIAID) [E] [b6]; Tolman, Brett <btolman@deloitte.com>; Corey MD, Larry [b6]
Subject: Re: ACTIV and antibodies

Along the same lines part and I have talked about eli Lilly who are really al in for mabs. I think laty wants them to join vaccines /mabs if they agree

Sent from my iPhone

On May 5, 2020, at 9:42 AM, Santos, Michael (FNIH) [T] [b6] wrote:

Hi John,

Thanks for raising this – indeed there's a lot of great inquiries about participation coming in.

At a general level, Ashley Parker is coordinating intake of questions like this from companies that are interested in engaging in ACTIV.

At a specific level, based on the conversation yesterday I believe that Mary and Mike are tracking the mAb space closely (at least the antiviral mAb space – if this is a host-directed mAb it may go better to the therapeutics group, but either way Ashley can route it for consideration).

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Mascola, John (NIH/VRC) [E] [b6]
Sent: Monday, May 4, 2020 9:39 PM
To: Santos, Michael (FNIH) [T] [b6]
Subject: ACTIV and antibodies

Mike,

Each time a talk to a company with COVID-19 product – they ask about ACTIV – so that is good!

A small company has a mAb product moving to phase 1 end of summer, to be used first at therapeutic.

Company is Brio Biosciences and head is Zhi Hong. [b6]

Is there a subgroup within ACTIV that has some focus on antibody therapeutics. And if so, can this company be invited?

Thanks
John

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 1/8/2021 6:40:56 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: FW: Notes from the Vaccines Sub-Group discussion on correlates
Attachments: 2020-12-18 Vaccines Clinical Trials Sub-Group meeting Notes.docx

Coming back at you, Cliff: please see the note below from Mike Santos addressing the conversations so far in the Vaccines WG about correlates of protection. I will make sure Doug and Mike get your note.

From: Santos, Michael (FNIH) [T] [b6]
Sent: Friday, January 8, 2021 12:10 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: Notes from the Vaccines Sub-Group discussion on correlates

Hi David,

On Dec 18 (a couple of days after the last Leadership Team meeting) we had a Vaccines Clinical Trials Sub-Group meeting on the topic of assessing correlates of protection.

The initial correlates analyses from the Moderna trial, based on the first 25 breakthrough cases, are expected roughly in April. The initial correlates studies will only look at antibodies because cellular data won't be available, but there is optimism based on the NHP IgG adoptive transfer studies by Dan Barouch that antibodies may be a sufficient correlate (though there is evidence that cellular immunity also contributes).

On a more technical note, the apparent clinical efficacy seen ~12 days after the first dose in the Pfizer and Moderna phase 3 trials is associated with a neutralizing titer that is around or below the lower limit of quantitation. That suggests a potential assay development need, though binding Ab assays have the dynamic range to cover those early response levels. The correlates analyses will look at both neutralization and binding.

The full notes (with presentations embedded) are attached. Doug will give an update at the Leadership Team meeting on Weds, and happy to answer any questions.

Thanks,
Mike

Michael Santos, PhD

Associate Vice President, Science

Foundation for the National Institutes of Health

b6

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From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 7/24/2020 9:01:54 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: questions about ACTIV email lists

Thank you! Have a nice weekend!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, July 24, 2020 4:33 PM
To: Brodd, Lauren (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: questions about ACTIV email lists

Here is the answer for Stacey's group and I have updated the spreadsheet.

Please let me know if you need anything else.

Cheryl

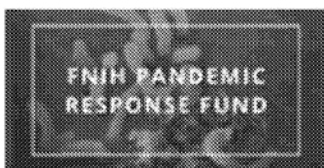
Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]

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From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, July 24, 2020 4:15 PM
To: Melencio, Cheryl (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6] Santos, Michael (FNIH) [T] [b6]
Subject: RE: questions about ACTIV email lists

Hi Cheryl,

To Joe's note, no need to add Felica.

- The following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Therapeutics Clinical WG member?

APAR0000006255

- [b6] – No need add she has ceased participating
- The following are listed on the ACTIV website as a Therapeutics Clinical WG members, but not on the WG tab in the excel file- should they be added in to the tab in the excel file?
 - [b6] Yes, please add to Excel
 - [b6] – Yes, please add to Excel

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, July 24, 2020 2:50 PM
To: Menetski, Joseph (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: FW: questions about ACTIV email lists

Hi all

I hate to bother you, but could you look at your relevant working groups and let me know your response My notes are in red

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 - [b6] – I know there was some correspondence about adding her to WGs but I can't find it
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 - [b6] – I don't have her on email distribution list, but she appears on the master list above
 - [b6] – see note above
- **Preclinical Tx WG tab:** the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Preclinical WG member?
 - [b6] – see note above
- **Clinical Trial Tx WG tab:**
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 - [b6]
 - The following are listed on the ACTIV website as a Therapeutics Clinical WG members, but not on the WG tab in the excel file- should they be added in to the tab in the excel file?
 - [b6]

Thank you

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

b6

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From: Brodd, Lauren (NIH/OD) [E] b6

Sent: Friday, July 24, 2020 1:34 PM

To: Melencio, Cheryl (FNIH) [T]

Cc: Parker, Ashley (NIH/OD) [E]

b6

Subject: questions about ACTIV email lists

Hi Cheryl,

We are working on updating the ACTIV website and relevant ACTIV files, and wanted to get clarification on several items related to your "Master and WG Email List for ACTIV" file (most recent version that we have is attached).

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- b6 (leadership)
- b6 (preclinical WG)
- b6 (therapeutics clinical WG)
- b6 (therapeutics clinical WG)
- b6 (therapeutics clinical WG)
- b6 (vaccines WG)
- b6 (providing support for ACTIV)
- b6 (providing support for ACTIV)
- b6: you had said he was only on one call representing AZ for Mene Pangalos. For our files, we wanted to double check whether or not he should be included in future emails?

- The following *are* on the Master Email list tab, but wanted to clarify for our records.

- b6 He was at earlier leadership meetings but not the most recent ones. Should he remain on the list and will he continue to be representing Gilead?
- b6 We don't have this person in our files. Is the person involved with a specific WG?

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- b6
-

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 - b6
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 - b6
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 - b6
 - The following are listed on the ACTIV website as a Therapeutics Clinical WG members, but not on the WG tab in the excel file- should they be added in to the tab in the excel file?
 - b6

Hope that all made sense. Let me know if you have any questions. Thanks so much!

Thanks,

Lauren

Lauren Brodd, Ph.D.
 Health Science Policy Analyst
 Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
 Office of Science Policy
 National Institutes of Health



OSP Blog: [Under the Poliscope](#)
 Twitter: [@CWolinetzNIH](#)

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 7/24/2020 8:25:34 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: questions about ACTIV email lists

Thanks for the updates!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, July 24, 2020 3:40 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: questions about ACTIV email lists

Here is the answer from Karen Tountas about Janet Woodcock on the Clinical Trial Capacity Working Group. (see below)

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
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From: Tountas, Karen (FNIH) [T] [b6]
Sent: Friday, July 24, 2020 3:33 PM
To: Menetski, Joseph (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: questions about ACTIV email lists

And Janet Woodcock left the WG to move over to OWS. She is no longer a WG member and should not be listed on the website.
Karen

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Friday, July 24, 2020 3:24 PM
To: Melencio, Cheryl (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: questions about ACTIV email lists

Felicia is our NIH Program officer for the OTA (money), is not a WG member, but is there to help us stay current with our OTA milestones and such.

I will leave the others for their teams.

Thank you for keeping this straight Cheryl.

From: Melencio, Cheryl (FNIH) [T] [b6]

Sent: Friday, July 24, 2020 2:50 PM

To: Menetski, Joseph (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]

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 - [b6]
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 - [b6]

Thank you

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]

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From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Friday, July 24, 2020 1:34 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E]
Subject: questions about ACTIV email lists

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- [b6] (vaccines WG)
- [b6] (providing support for ACTIV)
- [b6] (providing support for ACTIV)
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- [b6]
- [b6]

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- [b6]
- [b6]

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○

b6

- **Clinical Trial Tx WG tab:**

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▪

b6

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▪

b6

Hope that all made sense. Let me know if you have any questions. Thanks so much!

Thanks,

Lauren

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health

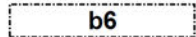


OSP Blog: [Under the Poliscopes](#)
Twitter: @CWolinetzNIH

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/24/2020 7:28:42 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: questions about ACTIV email lists

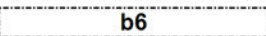
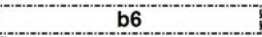
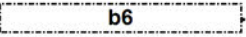
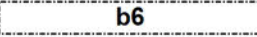
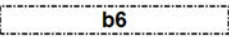
See note about Felicia Qashu from Joe Menetski

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

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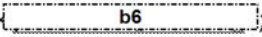

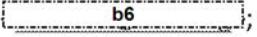
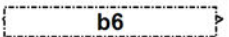


From: Menetski, Joseph (FNIH) [T]  b6
Sent: Friday, July 24, 2020 3:24 PM
To: Melencio, Cheryl (FNIH) [T]  b6; Tountas, Karen (FNIH) [T]  b6; Santos, Michael (FNIH) [T]  b6; Adam, Stacey (FNIH) [T]  b6
Subject: RE: questions about ACTIV email lists

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Cheryl Melencio
 Administrative Manager, Research Partnerships
 Foundation for the National Institutes of Health
 [b6]
fnih.org
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From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Friday, July 24, 2020 1:34 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E]
Subject: questions about ACTIV email lists

Hi Cheryl,

We are working on updating the ACTIV website and relevant ACTIV files, and wanted to get clarification on several items related to your "Master and WG Email List for ACTIV" file (most recent version that we have is attached).

- **Master Email List tab**

- The following *are not* currently on the Master Email list tab. According to the ACTIV website/our files, they are involved as indicated. Should they be added to the master email list tab?

- [b6] (leadership)
- [b6] (leadership)
- [b6] (preclinical WG)
- [b6] (therapeutics clinical WG)
- [b6] (therapeutics clinical WG)
- [b6] (therapeutics clinical WG)
- [b6] (vaccines WG)
- [b6] (providing support for ACTIV)
- [b6] (providing support for ACTIV)
- [b6] you had said he was only on one call representing AZ for Mene Pangalos. For our files, we wanted to double check whether or not he should be included in future emails?
- The following *are* on the Master Email list tab, but wanted to clarify for our records.
 - [b6] He was at earlier leadership meetings but not the most recent ones. Should he remain on the list and will he continue to be representing Gilead?
 - [b6] We don't have this person in our files. Is the person involved with a specific WG?

- **Vaccines WG tab**: the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Vaccines WG member?

- [b6]
- [b6]

- **Clinical Capacity WG tab**: the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Clinical Trial Capacity WG member?

- [b6]
- [b6]

- **Preclinical Tx WG tab**: the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Preclinical WG member?

- [b6]

- **Clinical Trial Tx WG tab**:

- The following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Therapeutics Clinical WG member?

- [b6]

- The following are listed on the ACTIV website as a Therapeutics Clinical WG members, but not on the WG tab in the excel file- should they be added in to the tab in the excel file?

- [b6]

Hope that all made sense. Let me know if you have any questions. Thanks so much!

Thanks,

Lauren

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health



OSP Blog: [Under the Poliscopes](#)

Twitter: @CWolinetzNIH

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 7/24/2020 7:19:56 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: questions about ACTIV email lists

Here are responses from Mike Santos for Vaccines WG – I have added [b6] to the master email list

- **Vaccines WG tab:** the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Vaccines WG member?
 - [b6] - I have her on distribution list but don't see her on working group list
 - [b6] - I know there was some correspondence about adding her to WGs but I can't find it

Neither should be added. Felicia Qashu is the NIH program officer for the NIH contract w/FNIH, which is why she shows up often. – Mike's response

- **Master Email List tab**
 - The following *are not* currently on the Master Email list tab. According to the ACTIV website/our files, they are involved as indicated. Should they be added to the master email list tab?
 - [b6] (vaccines WG)

Nelson is a Vaccines WG member and so should be on the Master Email list tab. – Mike's response

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Santos, Michael (FNIH) [T] <[b6]>
Sent: Friday, July 24, 2020 3:12 PM
To: Melencio, Cheryl (FNIH) [T] <[b6]>
Subject: RE: questions about ACTIV email lists

Hi Cheryl,

Here are my answers:

- **Vaccines WG tab**: the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Vaccines WG member?
 - [b6] - I have her on distribution list but don't see her on working group list
 - [b6] - I know there was some correspondence about adding her to WGs but I can't find it

Neither should be added. Felicia Qashu is the NIH program officer for the NIH contract w/FNIH, which is why she shows up often.

- **Master Email List tab**
 - The following *are not* currently on the Master Email list tab. According to the ACTIV website/our files, they are involved as indicated. Should they be added to the master email list tab?
 - * [b6] (vaccines WG)

Nelson is a Vaccines WG member and so should be on the Master Email list tab.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, July 24, 2020 2:50 PM
To: Menetski, Joseph (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: FW: questions about ACTIV email lists

Hi all

I hate to bother you, but could you look at your relevant working groups and let me know your response. My notes are in red

- **Vaccines WG tab**: the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Vaccines WG member?
 - [b6] - I have her on distribution list but don't see her on working group list
 - [b6] - I know there was some correspondence about adding her to WGs but I can't find it
- **Clinical Capacity WG tab**: the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Clinical Trial Capacity WG member?
 - [b6] - I don't have her on email distribution list, but she appears on the master list above
 - [b6] - see note above
- **Preclinical Tx WG tab**: the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Preclinical WG member?
 - [b6] - see note above
- **Clinical Trial Tx WG tab**:

- The following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Therapeutics Clinical WG member?

- [b6]

- The following are listed on the ACTIV website as a Therapeutics Clinical WG members, but not on the WG tab in the excel file- should they be added in to the tab in the excel file?

- [b6]

Thank you

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Friday, July 24, 2020 1:34 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: questions about ACTIV email lists

Hi Cheryl,

We are working on updating the ACTIV website and relevant ACTIV files, and wanted to get clarification on several items related to your "Master and WG Email List for ACTIV" file (most recent version that we have is attached).

- **Master Email List tab**

- The following *are not* currently on the Master Email list tab. According to the ACTIV website/our files, they are involved as indicated. Should they be added to the master email list tab?

- [b6] (leadership)
- [b6] (leadership)
- [b6] (preclinical WG)
- [b6] (therapeutics clinical WG)
- [b6] (therapeutics clinical WG)
- [b6] (therapeutics clinical WG)
- [b6] (vaccines WG)
- [b6] (providing support for ACTIV)
- [b6] (providing support for ACTIV)
- [b6] you had said he was only on one call representing AZ for Mene Pangalos. For our files, we wanted to double check whether or not he should be included in future emails?

- The following *are* on the Master Email list tab, but wanted to clarify for our records.

- [b6] He was at earlier leadership meetings but not the most recent ones. Should he remain on the list and will he continue to be representing Gilead?
 - [b6] We don't have this person in our files. Is the person involved with a specific WG?
- **Vaccines WG tab:** the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Vaccines WG member?
 - [b6]
 - **Clinical Capacity WG tab:** the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Clinical Trial Capacity WG member?
 - [b6]
 - **Preclinical Tx WG tab:** the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Preclinical WG member?
 - [b6]
 - **Clinical Trial Tx WG tab:**
 - The following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Therapeutics Clinical WG member?
 - [b6]
 - The following are listed on the ACTIV website as a Therapeutics Clinical WG members, but not on the WG tab in the excel file- should they be added in to the tab in the excel file?
 - [b6]

Hope that all made sense. Let me know if you have any questions. Thanks so much!

Thanks,

Lauren

Lauren Brodd, Ph.D.
 Health Science Policy Analyst
 Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
 Office of Science Policy
 National Institutes of Health



OSP Blog: [Under the Poliscope](#)
 Twitter: @CWolinetzNIH

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 7/24/2020 7:13:15 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: questions about ACTIV email lists

Thank you for the update!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, July 24, 2020 2:54 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E]
Subject: RE: questions about ACTIV email lists

I am not sure about some of the folks so I sent a note to the WG leads for clarification. I know

- **Master Email List tab**

- The following *are not* currently on the Master Email list tab. According to the ACTIV website/our files, they are involved as indicated. Should they be added to the master email list tab? I have added Kramer through Gadbois to the Master email list
 - [b6] (leadership)
 - [b6] (leadership)
 - [b6] (preclinical WG)
 - [b6] (therapeutics clinical WG)
 - [b6] (therapeutics clinical WG)
 - [b6] (therapeutics clinical WG)
 - [b6] (vaccines WG)
 - [b6] (providing support for ACTIV)
 - [b6] (providing support for ACTIV)
 - [b6]: you had said he was only on one call representing AZ for Mene Pangalos. For our files, we wanted to double check whether or not he should be included in future emails? Raburn Mallory was just a one time deal
- The following *are* on the Master Email list tab, but wanted to clarify for our records.
 - [b6] He was at earlier leadership meetings but not the most recent ones. Should he remain on the list and will he continue to be representing Gilead? No longer representing Gilead -- Tomas Cihlar is now on leadership team
 - [b6]: We don't have this person in our files. Is the person involved with a specific WG? Stephanie James works for FNIH she is Sr. Vice President, Science Dept. Michael Santos and Karen Tountas work for her.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]
fnihi.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Friday, July 24, 2020 1:59 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: questions about ACTIV email lists

Thanks so much!

Lauren

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, July 24, 2020 1:49 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: questions about ACTIV email lists

Let me go through the list and I'll get back to you

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Friday, July 24, 2020 1:34 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: questions about ACTIV email lists

Hi Cheryl,

We are working on updating the ACTIV website and relevant ACTIV files, and wanted to get clarification on several items related to your "Master and WG Email List for ACTIV" file (most recent version that we have is attached).

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- [b6] (leadership)
- [b6] (leadership)
- [b6] (preclinical WG)
- [b6] (therapeutics clinical WG)
- [b6] (therapeutics clinical WG)
- [b6] (therapeutics clinical WG)
- [b6] (vaccines WG)
- [b6] (providing support for ACTIV)
- [b6] (providing support for ACTIV)
- [b6] you had said he was only on one call representing AZ for Mene Pangalos. For our files, we wanted to double check whether or not he should be included in future emails?

- The following *are* on the Master Email list tab, but wanted to clarify for our records.

- [b6] He was at earlier leadership meetings but not the most recent ones. Should he remain on the list and will he continue to be representing Gilead?
- [b6] We don't have this person in our files. Is the person involved with a specific WG?

- **Vaccines WG tab:** the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Vaccines WG member?

- [b6]
- [b6]

- **Clinical Capacity WG tab:** the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Clinical Trial Capacity WG member?

- [b6]
- [b6]

- **Preclinical Tx WG tab:** the following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Preclinical WG member?

- [b6]

- **Clinical Trial Tx WG tab:**

- The following are listed on the WG tab, but not currently listed on the website. Should they be added to the ACTIV website as a Therapeutics Clinical WG member?

- [b6]

- The following are listed on the ACTIV website as a Therapeutics Clinical WG members, but not on the WG tab in the excel file- should they be added in to the tab in the excel file?

- [b6]

Hope that all made sense. Let me know if you have any questions. Thanks so much!

Thanks,

Lauren

Lauren Brodd, Ph.D.

Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health



OSP Blog: [Under the Poliscopes](#)
Twitter: @CWolinetzNIH

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 2/24/2021 5:06:09 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Updated ACTIV Working Members

Ok will do.

From: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Sent: Wednesday, February 24, 2021 11:16 AM
To: Brodd, Lauren (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: Updated ACTIV Working Members

Ok, I need to move this forward so I will take what I have.

Otherwise you should now have what you need to update the rosters and see who needs to be added the websites.

From: Brodd, Lauren (NIH/OD) [E] <[REDACTED] b6 >
Sent: Wednesday, February 24, 2021 11:07 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: Updated ACTIV Working Members

I hadn't gone through the list Cheryl sent (so didn't have the ones indicated with as asterisk for TRACE), but otherwise yes it matches what I have.

From: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Sent: Wednesday, February 24, 2021 10:52 AM
To: Brodd, Lauren (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: Updated ACTIV Working Members

Based on the information from Cheryl and Stacey, below is what I have for NIAID. Does this match your list? The asterisk represent those in the TRACE/Variant sub-WG which is technically new.

NIAID:

Alan Embry
Alkis Togias
Andrea Lerner
Ann Eakin
Clint Florence
Cliff Lane
Cristina Cassetti*
Elizabeth Church
Elizabeth Higgs
Emily Erbeling
Greg Dye
Hilary Marston
James McNamara
John Beigel

John Mascola
John Misasi*
Judy Hewitt
Julie Ledgerwood
Kimberly Stemple*
Liliana Brown*
Manizhe Payton
Mark Robien
Mary Marovich
Michael Proschan
Nancy Sullivan
Paula Bryant*
Peter Kim
Randy Tressler
Richard Koup
Sandra Sitar
Sarah Read
Seema Nayak

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, February 24, 2021 8:18 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Updated ACTIV Working Members

Yes, that's correct.

Remember you were the first to flag that there were NIAID staff on the WG's not on NIAID's original list — it was Michael Proschan. This is how we determined there were others who should be on the list but were somehow overlooked by NIAID.

On Feb 24, 2021, at 7:46 AM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Oh okay then yes I misunderstood. Based on our chat, I thought you only wanted to know people involved with ACTIV that were also on the NIAID award list, to cut down the award list (not to add people that the NIAID award list was missing... only for us to include people that were actually involved with ACTIV missing from Cheryl's list).

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, February 24, 2021 7:42 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Updated ACTIV Working Members

That was the point of the exercise — to identify who was missing from NIAID's original list but on the WG's and remove folks who were on their list but not on the WG's. I thought this was understood during our chat about this.

And Stacey indicated Laura McNay should not be listed as she's not on the WG.

*Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health*

APAR0000006265

Tel: [b6]

On Feb 24, 2021, at 7:37 AM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

This is what I was asking yesterday....do you also want the NIAID staff that were NOT on the NIAID original award list? Meaning you will be adding new people from ACTIV that were not on the original list? If so, then yes I have 28 total (not including Christine Sizemore)? So basically there are people involved with ACTIV that NIAID did not include on their award list, if that makes sense?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, February 24, 2021 7:35 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Updated ACTIV Working Members

Hi Lauren,

I think you may working off of an old thread — I have a total count of 28 NIAID awardees.

See my list to Stacey, her one removal and 7 additions including Christine Sizemore whom I need confirm works for FIC vs. NIAID.

Joe hasn't responded but I don't see anyone missing from the preclinical email threads I'm on — therefore this should cover it.

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Feb 24, 2021, at 7:23 AM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Hi Ashley,

From Stacey's list of 7 people, 5 of them were on the original NIAID award list, so adding those 5 to the other 17 we now have 22 people that are *both* involved with ACTIV and on the NIAID award list. I will note that I included Laura McNay- not sure what the final decision was based on the thread from Stacey to include her or not, but she was on NIAID awards list so maybe we leave her on?

Alkis Togias
Ann Eakin
Cliff Lane
Clint Florence
Elizabeth Church
Elizabeth Higgs
Emily Erbelding

Hilary Marston
James McNamara
John Beigel
John Mascola
Judy Hewitt
Laura McNay
Manizhe Payton
Mark Robien
Mary Marovich
Nancy Sullivan
Peter Kim
Randy Tressler
Sandra Sitar
Sarah Read
Seema Nayak

Are we still waiting for more from FNIH?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 7:27 PM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Brodd, Lauren (NIH/OD) [E]
Subject: Re: Updated ACTIV Working Members

Got it — thanks! I think Christine Sizemore is with FIC but should be included nonetheless.

Thanks — we'll still need an updated list of the working group and sub working group rosters whenever time permits.

Thanks,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Feb 23, 2021, at 7:21 PM, Adam, Stacey (FNIH) [T]
[b6] wrote:

Hi Ashley,

Apologies forgot about one of our groups. Here is a couple more NIAID reps:

James McNamara
Mark Robien
Christine Sizemore
Alkis Togias

Thanks,

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Tuesday, February 23, 2021 7:14 PM
To: Parker, Ashley (NIH/OD) [E]
[b6]; Menetski, Joseph (FNIH) [T]
Cc: Melencio, Cheryl (FNIH) [b6]
Brodd, Lauren (NIH/OD) [E]
Subject: RE: Updated ACTIV Working Members

Hi Ashley,

Additions from WG and Subgroups;
Nancy Sullivan
Greg Dye

Again, please let me know if you need the trial team lists, as I will need to reach out to ACTIV-2,3, and 5. Notably: Laura McNay should likely be included for her role in ACTIV-3 even though she is not an ACTIV WG member.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: (301) 318-8310

From: Parker, Ashley (NIH/OD) [E]
[b6]
Sent: Tuesday, February 23, 2021 6:49 PM
To: Adam, Stacey (FNIH) [T]; [b6]
Menetski, Joseph (FNIH) [T]; [b6]
Cc: Melencio, Cheryl (FNIH) [T]; [b6]
Brodd, Lauren (NIH/OD) [E]; [b6]
Subject: Updated ACTIV Working Members

Hi Stacey and Joe,

I think Cheryl reached out to you today to ask for an updated list of participants in the working groups. We are submitting an award for ACTIV and I need to ensure

I have all the folks from NIAID. I have staff from the other ICs.

Can we please have this list or please confirm if we are missing anyone from NIAID provided below?

This information will also be useful to have as we aim to keep participants updated on the website and when we receive such request from congressional members. Cheryl is very good about pinging us when there are additions but I think some folks were not added to our master roster during some of the hectic weeks (which has been practically every week for a while!).

NIAID:

Alan Embry
Andrea Lerner
Ann Eakin
Clint Florence
Cliff Lane
Elizabeth Church
Elizabeth Higgs
Emily Erbeling
Hilary Marston
Jim Neaton
John Beigel
John Mascola
Judy Hewitt
Julie Ledgerwood
Manizhe Payton
Mary Marovich
Michael Proschan
Peter Kim
Randy Tressler
Sandra Sitar
Sarah Read
Seema Nayak

Thanks,
Ashley

Ashley Parker, Ph.D.

Office of the Director | National Institutes of Health

Tel: b6

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/24/2021 12:28:22 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Updated ACTIV Working Members

Thanks, Ashley,

We will have it to Cheryl to send to you tomorrow.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 7:27 PM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6] Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Updated ACTIV Working Members

Got it — thanks! I think Christine Sizemore is with FIC but should be included nonetheless.

Thanks — we'll still need an updated list of the working group and sub working group rosters whenever time permits.

Thanks,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Feb 23, 2021, at 7:21 PM, Adam, Stacey (FNIH) [T] [b6] wrote:

Hi Ashley,

Apologies forgot about one of our groups. Here is a couple more NIAID reps:
James McNamara
Mark Robien

Christine Sizemore
Alkis Togias

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Tuesday, February 23, 2021 7:14 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Menetski, Joseph (FNIH) [T]
[b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6] Brodd, Lauren (NIH/OD) [E]
[b6]
Subject: RE: Updated ACTIV Working Members

Hi Ashley,

Additions from WG and Subgroups;
Nancy Sullivan
Greg Dye

Again, please let me know if you need the trial team lists, as I will need to reach out to ACTIV-2,3, and 5.
Notably: Laura McNay should likely be included for her role in ACTIV-3 even though she is not an ACTIV WG member.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 6:49 PM
To: Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6] Brodd, Lauren (NIH/OD) [E]
[b6]
Subject: Updated ACTIV Working Members

Hi Stacey and Joe,

I think Cheryl reached out to you today to ask for an updated list of participants in the working groups. We are submitting an award for ACTIV and I need to ensure I have all the folks from NIAID. I have staff from the other ICs.

Can we please have this list or please confirm if we are missing anyone from NIAID provided below?

This information will also be useful to have as we aim to keep participants updated on the website and when we receive such request from congressional members. Cheryl is very good about pinging us when there are additions but I think some folks were not added to our master roster during some of the hectic weeks (which has been practically every week for a while!).

NIAID:

Alan Embry
Andrea Lerner
Ann Eakin
Clint Florence
Cliff Lane
Elizabeth Church
Elizabeth Higgs
Emily Erbeling
Hilary Marston
Jim Neaton
John Beigel
John Mascola
Judy Hewitt
Julie Ledgerwood
Manizhe Payton
Mary Marovich
Michael Proschan
Peter Kim
Randy Tressler
Sandra Sitar
Sarah Read
Seema Nayak

Thanks,
Ashley

Ashley Parker, Ph.D.

Office of the Director | National Institutes of Health

Tel: b6

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 2/24/2021 12:22:21 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Updated ACTIV Working Members

Hi Ashley,

Laura is not a member of the WGs only the trial, so I leave that up to the submitters. She has been key for the trials.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 7:20 PM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Updated ACTIV Working Members

Thanks, Stacey! To be clear, I am removing Jim Neaton and adding Nancy S. and Greg? Or you also want to add Laura McNay?

Ashley

Ashley Parker, Ph.D.

Office of the Director | National Institutes of Health

Tel: [b6]

On Feb 23, 2021, at 7:14 PM, Adam, Stacey (FNIH) [T] [b6] wrote:

Thanks, Ashley,

Just sent you my additions then.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 7:08 PM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T]
[b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Updated ACTIV Working Members

Hi Stacey,

Given the time constraints and request to keep it concise, the ACTIV WGs and subgroups should be sufficient. We've encouraged the ICs to submit their IC specific awards to include all those involved on the trials which we understand is extensive.

Thanks for the note about Jim Neaton!

Ashley

Ashley Parker, Ph.D.

Office of the Director | National Institutes of Health

Tel: [b6]

On Feb 23, 2021, at 7:02 PM, Adam, Stacey (FNIH) [T] [b6] wrote:

Hi Ashley,

A question and a note to ensure that we catch everyone. Do you want just those with in ACTIV WG and subgroups, or do you need the NIAID folks on the trials as well. The second will be much harder.

Note: Jim Neaton is the PI for INSIGHT, but works at U of MN not NIAID.

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 6:49 PM
To: Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T]
[b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6] Brodd, Lauren (NIH/OD) [E]

b6

Subject: Updated ACTIV Working Members

Hi Stacey and Joe,

I think Cheryl reached out to you today to ask for an updated list of participants in the working groups. We are submitting an award for ACTIV and I need to ensure I have all the folks from NIAID. I have staff from the other ICs.

Can we please have this list or please confirm if we are missing anyone from NIAID provided below?

This information will also be useful to have as we aim to keep participants updated on the website and when we receive such request from congressional members. Cheryl is very good about pinging us when there are additions but I think some folks were not added to our master roster during some of the hectic weeks (which has been practically every week for a while!).

NIAID:

Alan Embry
Andrea Lerner
Ann Eakin
Clint Florence
Cliff Lane
Elizabeth Church
Elizabeth Higgs
Emily Erbelding
Hilary Marston
Jim Neaton
John Beigel
John Mascola
Judy Hewitt
Julie Ledgerwood
Manizhe Payton
Mary Marovich
Michael Proschan
Peter Kim
Randy Tressler
Sandra Sitar
Sarah Read
Seema Nayak

Thanks,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health

Tel: b6

APAR0000006269

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 2/24/2021 12:12:17 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

So 22 was all NIAID on ACTIV rosters, with 17 of those on the NIAID list for the award.

From: Brodd, Lauren (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 7:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

The 5 people are those from Cheryl that are involved with ACTIV from NIAID but NOT on the NIAID list for the award.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 6:15 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Emailing: Master and WG Email List for ACTIV rv19February2021

Sorry, what 5 members did you mention? I'm totally confused now.

I sent 22 names and asked to cross check with the additional list Cheryl will be sending which hasn't been received yet.

On Feb 23, 2021, at 5:01 PM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Was just confirming that you don't want to *add* any NIAID members (like the 5 I mentioned below that are involved with ACTIV but not on the NIAID award list)...I'm guessing the answer is no since the point of this is to limit, not add to, the list, but just wanted to make sure. The 17 names I sent you is a list of people that *both* appear on the ACTIV list as well as the NIAID award list. So that is the most complete list we have at the moment.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 4:28 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Emailing: Master and WG Email List for ACTIV rv19February2021

We are basically accounting for every NIAID staff member who participates in ACTIV based on the rosters.

Some of these names are on NIAID's original list and some were missing as you've indicated.

If confusing, let's chat about it when you're free.

Thanks,

Ashley

On Feb 23, 2021, at 4:04 PM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Just in case you get the info from Cheryl while I'm gone getting Mason (since I know you wanted to submit this today), I crossed checked what we have so far (names you listed below). Of the NIAID ACTIV members, these also appear on the NIAID award list:

Ann Eakin
Clint Florence
Cliff Lane
Elizabeth Church
Elizabeth Higgs
Emily Erbelding
Hilary Marston
John Beigel
John Mascola
Judy Hewitt
Manizhe Payton
Mary Marovich
Peter Kim
Randy Tressler
Sandra Sitar
Sarah Read
Seema Nayak

So in total we have 22 members from NIAID involved in ACTIV, with the above 17 on the NIAID list (5 do not appear on the list).

From: Brodd, Lauren (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 3:34 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Just to confirm, you only want to know people that appear on NIAID awards list, correct? For example, Alan Embry is on your list below (so involved with ACTIV), but not on the NIAID awards list, so he should not be included in the final list?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 3:13 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Below is what I have thus far from emails and Cheryl's vaccine list. Can you cross check these and add the NIAID names from the Tx clinical rosters/preclinical that Cheryl will be sending?

NIAID:
Alan Embry
Andrea Lerner

APAR0000006277

Ann Eakin
Clint Florence
Cliff Lane
Elizabeth Church
Elizabeth Higgs
Emily Erbelding
Hilary Marston
Jim Neaton
John Beigel
John Mascola
Judy Hewitt
Julie Ledgerwood
Manizhe Payton
Mary Marovich
Michael Proschan
Peter Kim
Randy Tressler
Sandra Sitar
Sarah Read
Seema Nayak

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 1:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Yes

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 12:59 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Do you have a min to chat?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:57 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Looking at the attached email threads to the WG's (specially staff with NIAID emails), I am afraid members have been added to the WG's but maybe not shared with Cheryl?

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 12:46 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

I don't see Peter or Ann in the excel file. I also don't see Ann on the website for the Tx clinical WG: <https://www.nih.gov/research-training/medical-research-initiatives/activ/therapeutics-clinical-working-group?>

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 12:43 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Ann Eakin is on the Tx clinical WG – does she show up?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:41 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

I worked with Peter Kim on the ACTIV-2 request for machines and testing kits – is he missing?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:38 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Nancy Sullivan looks familiar too or am I mistaken? Seems she was on the vaccines WG?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:34 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

We are missing folks from NIAID – John Biegel leads ACTIV-5. Did Cheryl not add him to the roster?

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:57 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Ashley,

I went through the roster, and these people that are on the ACTIV roster and also on the NIAID list below:

Clint Florence
Judith Hewitt
Elizabeth Higgs
Emily Erbeling
Cliff Lane
Hilary Marston
John Mascola
Sarah Read
Seema Nayak
Manizhe Payton

Also just an FYI that there is one person (aside from Tony Fauci) that is on the ACTIV roster from NIAID but not on the list below: Michael Proshan.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6] >
Sent: Tuesday, February 23, 2021 11:18 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Thanks!

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:17 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Yes will do and let you know this afternoon.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:00 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Lauren,

NIAID submitted the names below for the ACTIV award however NIH leadership has requested that this list be significantly cut down. Can you identify those who are currently listed on our ACTIV rosters from NIAID?

NIAID:

Adriana Andrade
Tia Morton
Ahsen Khan
Aileene Lewis
Akin Ojumu
Alisa Khomyanina
Alissa Burkey
Alkis Togias
Amy Adams
Andy Cherry
Ann Eakin
Aroussiak Bowen
Arzhang Cyrus Javan
Audria Crowder
Bariatu Smith

Beth Baseler
Betsey Herpin
Bobby Corno
Bola Adedeji
Callie Prassinis
Calvin Proffitt
Carmelle Norice-Tra
Carol Ostrye
Carol Worrell
Carole Andres
Charles Hackett
Charles Oluremi
Chase Sullivan
Christine Czarniecki
Claudia Baxter
Connie Suders
Conrad Mallia
Cynthia Osborne
Dan Curtin
Daniella Livnat
Dara Potter
Darlene Fitch
David Vallee
Denise Shelley
Dhawala Kovuri
Donna Germuga
Eileen Chang
Eileen Lake
Eileen Webster-Cissel
Elizabeth Church
Elizabeth Grace
Elizabeth Heredia
Elizabeth Higgs
Ellen Goldmuntz
Emily Erbeling
Erica Brittain
Esther Akpa
Grace Kelly
Grace Nissao
Greg Deye
Gregory Gendron
Guinevere Chun
Hamed Makou
Heather Deckert
Hilary Marston
Hyung Koo
Irene Rwakazina
Jackie Burns
Jaclyn Evans
Jake Stein
James McNamara
Jamila Aboulhab
Janet O'Brien

Janice Arega
Jen Sandrus
Jenna Briggs
Jennifer Cash
Jensen Gertz
Jerome Pierson
John Beigel
John Mascola
John Misasi
John Tierney
Jonathan Green
Jorge Mejia-Galvis
Josh Lorenzo
Joy Beeler
Judith Zuckerman
Jui Shah
Karen Reese
Katy Saliba
Keisha Johnson
Kelly Cahill
Kelly Parsons
Kevin Barrett
Kim Brookens
Larry Chen
Laura McNay
Leah MacDonald
Lei Huang
Liam Harmon
Linda Ehler
Lindsey Yeon
Lisa Giebeig
Lisa Hoopengardner
Lizanne Selthoffer
Lorraine Waring
Lynda Huber
Lyudmila Lyakh
Manizhe Payton
Marc Teitelbaum
Margarita Gomez
Mark Mishkin
Mark Robien
Martin Johnson
Martin McPhee
Mary Marovich
Mary Smolskis
Mary Wright
Maryam Jahromi
MaryAnne Luzar
Matthew Kirchoff
Maxwell Rajan
Meryna Manandhar
Mi Ha Kim
Michael Finn

Michael Galcik
Michael Welsh
Michelle Conan-Cibotti
Michelle Wildman
Molly Buehn
Nancy Bridges
Nancy Sullivan
Neelam Gulati
Odav Jallah
Onyinye Erundu
Ousmane Toure
Page Crew
Patrice Becker
Patricia Gottdiener
Peter Kim
Preston Holley
Randy Tressler
Ratna Sardana
Rebecca Mock
Rick Koup
Rob Palmer
Rona Siskind
Ruth Ebiasah
Sanaz Hamrah
Sandra Sitar
Sarah Read
Scott Garrand
Seema Nayak
Shamay Knox
Shane Ryan
Sharon Segal Raim
Shelly Simpson
Shere Billouin Frazier
Sindhu Gopalan
Sonia Gales
Stacy Kopka
Susan Vogel
Suzanne Dolney
Tammy Yokum
Teri Lewis
Theresa Engel
Thucuma Sise
Tseday Girma
Vanessa Eccard Koons
Victoria Wulah
Wade Green
William Erhardt
Yette Asfaw
Yin Li
Yvonne Jato
Swee Teo
Brian Madgey
Stanley Knight

Clint Florence
Judy Hewitt
Ann Eakin
Paula Bryant
Liliana Brown
Rick Sciotti
Mark Challberg
Mindy Davis
Greg Deye
Carl Dieffenbach
Cliff Lane

Thanks,
Ashley

From: Brodd, Lauren (NIH/OD) [E] { b6 }
Sent: Friday, February 19, 2021 5:28 PM
To: Parker, Ashley (NIH/OD) [E] { b6 }
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Thanks, and same to you!

From: Parker, Ashley (NIH/OD) [E] { b6 }
Sent: Friday, February 19, 2021 5:26 PM
To: Brodd, Lauren (NIH/OD) [E] { b6 }
Subject: Re: Emailing: Master and WG Email List for ACTIV rv19February2021

Got it — thanks and have a good weekend!

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: { b6 }

On Feb 19, 2021, at 4:00 PM, Brodd, Lauren (NIH/OD) [E] { b6 } wrote:

Hi Ashley,

I didn't respond to Cheryl, but just an FYI that I looked back over my emails and we had asked a few times to use our excel. I think for whatever reason she prefers using hers, which is fine (maybe it is easier for her purposes to just have the emails). I will just make sure to make the changes on our version too (there aren't a ton of changes anymore so I don't think that is an issue), and keep it up-to-date with complete information (titles, degrees, etc).

Thanks,

Lauren

-----Original Message-----

From: Melencio, Cheryl (FNIH) [T] b6
Sent: Friday, February 19, 2021 3:48 PM
To: Parker, Ashley (NIH/OD) [E] b6
Cc: Brodd, Lauren (NIH/OD) [E] b6
Subject: Emailing: Master and WG Email List for ACTIV
rv19February2021

Hi Ashley

There have been a couple changes to the leadership team.

Andy Plump, Takeda has asked that Rajeev Venkayya attend the Leadership meetings in his place. Rajeev Venkayya, MD, President, Global Vaccine Business Unit, Takeda
Rachel Ramoni, VA has asked that Victoria Davey attend Leadership meetings in her place. Victoria Davey, PhD, MPH, Chief Research & Development Officer for Public Health and Epidemiology, U. S. Department of Veterans Affairs

I have updated the spread sheet.

Cheryl

Your message is ready to be sent with the following file or link attachments:

Master and WG Email List for ACTIV rv19February2021

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

<Master and WG Email List for ACTIV rv19February2021.xlsx>

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 2/24/2021 12:39:24 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Updated ACTIV Working Members

These are the people I am referring to, along with Christine Sizemore

Alan Embry
Andrea Lerner
Jim Neaton
Julie Ledgerwood
Michael Proschan
Greg Dye

From: Brodd, Lauren (NIH/OD) [E]
Sent: Wednesday, February 24, 2021 7:38 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Updated ACTIV Working Members

This is what I was asking yesterday....do you also want the NIAID staff that were NOT on the NIAID original award list? Meaning you will be adding new people from ACTIV that were not on the original list? If so, then yes I have 28 total (not including Christine Sizemore)? So basically there are people involved with ACTIV that NIAID did not include on their award list, if that makes sense?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, February 24, 2021 7:35 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Updated ACTIV Working Members

Hi Lauren,

I think you may working off of an old thread — I have a total count of 28 NIAID awardees.

See my list to Stacey, her one removal and 7 additions including Christine Sizemore whom I need confirm works for FIC vs. NIAID.

Joe hasn't responded but I don't see anyone missing from the preclinical email threads I'm on — therefore this should cover it.

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Feb 24, 2021, at 7:23 AM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Hi Ashley,

From Stacey's list of 7 people, 5 of them were on the original NIAID award list, so adding those 5 to the other 17 we now have 22 people that are *both* involved with ACTIV and on the NIAID award list. I will note that I included Laura McNay- not sure what the final decision was based on the thread from Stacey to include her or not, but she was on NIAID awards list so maybe we leave her on?

Alkis Togias
Ann Eakin
Cliff Lane
Clint Florence
Elizabeth Church
Elizabeth Higgs
Emily Erbelding
Hilary Marston
James McNamara
John Beigel
John Mascola
Judy Hewitt
Laura McNay
Manizhe Payton
Mark Robien
Mary Marovich
Nancy Sullivan
Peter Kim
Randy Tressler
Sandra Sitar
Sarah Read
Seema Nayak

Are we still waiting for more from FNIH?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 7:27 PM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T]
[b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Updated ACTIV Working Members

Got it — thanks! I think Christine Sizemore is with FIC but should be included nonetheless.

Thanks — we'll still need an updated list of the working group and sub working group rosters whenever time permits.

Thanks,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Feb 23, 2021, at 7:21 PM, Adam, Stacey (FNIH) [T] [b6] wrote:

Hi Ashley,

Apologies forgot about one of our groups. Here is a couple more NIAID reps:

James McNamara
Mark Robien
Christine Sizemore
Alkis Togias

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]

Sent: Tuesday, February 23, 2021 7:14 PM

To: Parker, Ashley (NIH/OD) [E] [b6]; Menetski, Joseph (FNIH) [T]

[b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Brodd, Lauren (NIH/OD) [E]
[b6]

Subject: RE: Updated ACTIV Working Members

Hi Ashley,

Additions from WG and Subgroups;
Nancy Sullivan
Greg Dye

Again, please let me know if you need the trial team lists, as I will need to reach out to ACTIV-2,3, and 5.

Notably: Laura McNay should likely be included for her role in ACTIV-3 even though she is not an ACTIV WG member.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Tuesday, February 23, 2021 6:49 PM

To: Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T]

[b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Brodd, Lauren (NIH/OD) [E]
[b6]

Subject: Updated ACTIV Working Members

Hi Stacey and Joe,

I think Cheryl reached out to you today to ask for an updated list of participants in the working groups. We are submitting an award for ACTIV and I need to ensure I have all the folks from NIAID. I have staff from the other ICs.

Can we please have this list or please confirm if we are missing anyone from NIAID provided below?

This information will also be useful to have as we aim to keep participants updated on the website and when we receive such request from congressional members. Cheryl is very good about pinging us when there are additions but I think some folks were not added to our master roster during some of the hectic weeks (which has been practically every week for a while!).

NIAID:

Alan Embry
Andrea Lerner
Ann Eakin
Clint Florence
Cliff Lane
Elizabeth Church
Elizabeth Higgs
Emily Erbeling
Hilary Marston
Jim Neaton
John Beigel
John Mascola
Judy Hewitt
Julie Ledgerwood
Manizhe Payton
Mary Marovich
Michael Proschan
Peter Kim
Randy Tressler
Sandra Sitar
Sarah Read
Seema Nayak

Thanks,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: b6

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 2/23/2021 6:34:45 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021
Attachments: Re: ACTIV Therapeutics-Clinical Working Group; Re: Scheduling an ACTIV TX-Clinical Agent Prioritization Subgroup Meeting; Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Cheryl,

Hope you had a nice weekend!

We need to compile a list of people from NIAID that are involved with ACTIV. In doing this, we noticed that there are people who are on working group emails (see attached examples) but are not on the master roster list (version you sent on Friday is attached, and these people don't appear to be on 'master' or 'WG' tabs). For example, John Biegel, Ann Eakin, and Randall Tressler are on the WG email threads, but not on the master excel file. There could be others, but those are the ones we have happen to notice.

Based on this, are there additional people on the WGs that are not in the master excel file? Do you have current rosters for the WGs? If there is any way you could let us know today, it would be much appreciated!

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, February 19, 2021 5:26 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: Re: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Cheryl!

Long time! I hope all is well!

Thank you for the updates. We will make the updates on our version of the excel sheet we updated and shared several months back.

Thanks and have a great weekend!
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Feb 19, 2021, at 3:48 PM, Melencio, Cheryl (FNIH) [T] [b6] wrote:

Hi Ashley

There have been a couple changes to the leadership team.

Andy Plump, Takeda has asked that Rajeev Venkayya attend the Leadership meetings in his place. Rajeev Venkayya, MD, President, Global Vaccine Business Unit, Takeda
Rachel Ramoni, VA has asked that Victoria Davey attend Leadership meetings in her place. Victoria Davey, PhD, MPH, Chief Research & Development Officer for Public Health and Epidemiology, U. S. Department of Veterans Affairs

I have updated the spread sheet.

Cheryl

Your message is ready to be sent with the following file or link attachments:

Master and WG Email List for ACTIV rv19February2021

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

<Master and WG Email List for ACTIV rv19February2021.xlsx>

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 2/23/2021 5:48:41 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

I also don't see Nancy on the Vaccines WG website: <https://www.nih.gov/research-training/medical-research-initiatives/activ/vaccines-working-group>

From: Brodd, Lauren (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:46 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

I don't see Peter or Ann in the excel file. I also don't see Ann on the website for the Tx clinical WG:
<https://www.nih.gov/research-training/medical-research-initiatives/activ/therapeutics-clinical-working-group?>

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 12:43 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Ann Eakin is on the Tx clinical WG – does she show up?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:41 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

I worked with Peter Kim on the ACTIV-2 request for machines and testing kits – is he missing?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:38 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Nancy Sullivan looks familiar too or am I mistaken? Seems she was on the vaccines WG?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:34 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

We are missing folks from NIAID – John Biegel leads ACTIV-5. Did Cheryl not add him to the roster?

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:57 AM

To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Ashley,

I went through the roster, and these people that are on the ACTIV roster and also on the NIAID list below:

Clint Florence
Judith Hewitt
Elizabeth Higgs
Emily Erbeling
Cliff Lane
Hilary Marston
John Mascola
Sarah Read
Seema Nayak
Manizhe Payton

Also just an FYI that there is one person (aside from Tony Fauci) that is on the ACTIV roster from NIAID but not on the list below: Michael Proschan.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:18 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Thanks!

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:17 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Yes will do and let you know this afternoon.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:00 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Lauren,

NIAID submitted the names below for the ACTIV award however NIH leadership has requested that this list be significantly cut down. Can you identify those who are currently listed on our ACTIV rosters from NIAID?

NIAID:

Adriana Andrade
Tia Morton
Ahsen Khan
Aileene Lewis
Akin Ojumu
Alisa Khomyanina
Alissa Burkey
Alkis Togias
Amy Adams
Andy Cherry
Ann Eakin
Aroussiak Bowen
Arzhang Cyrus Javan
Audria Crowder
Bariatu Smith
Beth Baseler
Betsey Herpin
Bobby Corno
Bola Adedeji
Callie Prassinis
Calvin Proffitt
Carmelle Norice-Tra
Carol Ostrye
Carol Worrell
Carole Andres
Charles Hackett
Charles Oluremi
Chase Sullivan
Christine Czarniecki
Claudia Baxter
Connie Suders
Conrad Mallia
Cynthia Osborne
Dan Curtin
Daniella Livnat
Dara Potter
Darlene Fitch
David Vallee
Denise Shelley
Dhawala Kovuri
Donna Germuga
Eileen Chang
Eileen Lake
Eileen Webster-Cissel
Elizabeth Church
Elizabeth Grace
Elizabeth Heredia
Elizabeth Higgs
Ellen Goldmuntz
Emily Erbeling
Erica Brittain
Esther Akpa

Grace Kelly
Grace Nissao
Greg Deye
Gregory Gendron
Guinevere Chun
Hamed Makou
Heather Deckert
Hilary Marston
Hyung Koo
Irene Rwakazina
Jackie Burns
Jaclyn Evans
Jake Stein
James McNamara
Jamila Aboulhab
Janet O'Brien
Janice Arega
Jen Sandrus
Jenna Briggs
Jennifer Cash
Jensen Gertz
Jerome Pierson
John Beigel
John Mascola
John Misasi
John Tierney
Jonathan Green
Jorge Mejia-Galvis
Josh Lorenzo
Joy Beeler
Judith Zuckerman
Jui Shah
Karen Reese
Katy Saliba
Keisha Johnson
Kelly Cahill
Kelly Parsons
Kevin Barrett
Kim Brookens
Larry Chen
Laura McNay
Leah MacDonald
Lei Huang
Liam Harmon
Linda Ehler
Lindsey Yeon
Lisa Giebeig
Lisa Hoopengardner
Lizanne Selthoffer
Lorraine Waring
Lynda Huber
Lyudmila Lyakh
Manizhe Payton

Marc Teitelbaum
Margarita Gomez
Mark Mishkin
Mark Robien
Martin Johnson
Martin McPhee
Mary Marovich
Mary Smolskis
Mary Wright
Maryam Jahromi
MaryAnne Luzar
Matthew Kirchoff
Maxwell Rajan
Meryna Manandhar
Mi Ha Kim
Michael Finn
Michael Galcik
Michael Welsh
Michelle Conan-Cibotti
Michelle Wildman
Molly Buehn
Nancy Bridges
Nancy Sullivan
Neelam Gulati
Odav Jallah
Onyinye Erundu
Ousmane Toure
Page Crew
Patrice Becker
Patricia Gottdiener
Peter Kim
Preston Holley
Randy Tressler
Ratna Sardana
Rebecca Mock
Rick Koup
Rob Palmer
Rona Siskind
Ruth Ebiasah
Sanaz Hamrah
Sandra Sitar
Sarah Read
Scott Garrand
Seema Nayak
Shamay Knox
Shane Ryan
Sharon Segal Raim
Shelly Simpson
Shere Billouin Frazier
Sindhu Gopalan
Sonia Gales
Stacy Kopka
Susan Vogel

Suzanne Dolney
Tammy Yokum
Teri Lewis
Theresa Engel
Thucuma Sise
Tseday Girma
Vanessa Eccard Koons
Victoria Wulah
Wade Green
William Erhardt
Yette Asfaw
Yin Li
Yvonne Jato
Swee Teo
Brian Madgey
Stanley Knight
Clint Florence
Judy Hewitt
Ann Eakin
Paula Bryant
Liliana Brown
Rick Sciotti
Mark Challberg
Mindy Davis
Greg Deye
Carl Dieffenbach
Cliff Lane

Thanks,
Ashley

From: Brodd, Lauren (NIH/OD) [E]: [b6]
Sent: Friday, February 19, 2021 5:28 PM
To: Parker, Ashley (NIH/OD) [E]: [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Thanks, and same to you!

From: Parker, Ashley (NIH/OD) [E]: [b6]
Sent: Friday, February 19, 2021 5:26 PM
To: Brodd, Lauren (NIH/OD) [E]: [b6]
Subject: Re: Emailing: Master and WG Email List for ACTIV rv19February2021

Got it — thanks and have a good weekend!

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Feb 19, 2021, at 4:00 PM, Brodd, Lauren (NIH/OD) [E]: [b6] wrote:

Hi Ashley,

I didn't respond to Cheryl, but just an FYI that I looked back over my emails and we had asked a few times to use our excel. I think for whatever reason she prefers using hers, which is fine (maybe it is easier for her purposes to just have the emails). I will just make sure to make the changes on our version too (there aren't a ton of changes anymore so I don't think that is an issue), and keep it up-to-date with complete information (titles, degrees, etc).

Thanks,

Lauren

-----Original Message-----

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, February 19, 2021 3:48 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Ashley

There have been a couple changes to the leadership team.

Andy Plump, Takeda has asked that Rajeev Venkayya attend the Leadership meetings in his place. Rajeev Venkayya, MD, President, Global Vaccine Business Unit, Takeda
Rachel Ramoni, VA has asked that Victoria Davey attend Leadership meetings in her place. Victoria Davey, PhD, MPH, Chief Research & Development Officer for Public Health and Epidemiology, U. S. Department of Veterans Affairs

I have updated the spread sheet.

Cheryl

Your message is ready to be sent with the following file or link attachments:

Master and WG Email List for ACTIV rv19February2021

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

<Master and WG Email List for ACTIV rv19February2021.xlsx>

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 5/14/2020 6:42:05 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]
CC: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]
Subject: RE: additional emails for ACTIV working group permission

I have Clint added to the list now. He must have slipped through the cracks. He is there now.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] b6
Sent: Thursday, May 14, 2020 2:40 PM
To: Gorman, Greta (FNIH) [T] b6
Cc: Meltzer, Abbey (FNIH) [T] b6; Melencio, Cheryl (FNIH) [T] b6
Subject: RE: additional emails for ACTIV working group permission

Hi Greta,

Thank you so much for flagging this. I will let Dr. Collins know to send to these members. I noticed you had an additional member, Clint Florence not included in the list Cheryl provided – can we confirm before I send forward?

Thank you,
Ashley

Preclinical

Adams, Peter (OS/ASPR/BARDA) b6
Anderson, Annaliesa b6
Baric, Ralph b6

APAR0000006384

Carter, Kara <[b6]>
Colvis, Christine <[b6]>
Deming, Damon (FDA/CDER) <[b6]>
Diamond, Michael <[b6]>
Duncan, Ken <[b6]>
Fernandes, Prabhavathi <[b6]>
Gatto, Greg <[b6]>
Grobler, Jay <[b6]>
Hewitt, Judith <[b6]>
Jonson, Samantha (NIH/NCATS) [E]
<[b6]>
Lutz, Cat <[b6]>

Nestle, Frank <[b6]>
Ottinger, Liz <[b6]>
Payne, David <[b6]>
Rao, Srinivas<[b6]>
Rappaport, Jay <[b6]>
Stegmeier, Frank <[b6]>
Young, John <[b6]>
Qashu, Felicia <[b6]>
Pitt, Louise<[b6]>;
Cihlar, Tomas <[b6]>
Fessel, Josh <[b6]>
Punturieri, Tony<[b6]>;
Charette, Marc <[b6]>
Florence, Clint (NIH/NIAID) [E] <[b6]>

From: Gorman, Greta (FNIH) [T] <[b6]>
Sent: Thursday, May 14, 2020 1:23 PM
To: Parker, Ashley (NIH/OD) [E] <[b6]>
Cc: Meltzer, Abbey (FNIH) [T] <[b6]>
Subject: additional emails for ACTIV working group permission

Dear Ashley,

We just cross checked the WG rosters we have with the emails that NIH sent out to members seeking permission to be included on the website.

No email was included for the four members below. I also don't believe any of the members of the Preclinical WG were contacted—those email addresses are attached.

Let me know if you have any questions.

Thanks!
Greta

Vaccines

APAR0000006384

Beth Bell, M.D., MPH

Clinical Professor, Global Health
University of Washington

b6

Jonathan Seals, Ph.D.

Director, Strategic Science and Technology
Biomedical Advanced Research and Development Authority

b6

Therapeutics—Clinical

Sylva Collins, Ph.D.

Director, Office of Biostatistics
U.S. Food and Drug Administration

b6

Yves Rosenberg, M.D., MPH

Branch Chief, Atherothrombosis and Coronary Artery Disease Branch
National Heart, Lung, and Blood Institute, NIH

b6

Greta Gorman

Director of Communications

Foundation for the National Institutes of Health

b6

fniih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 8/31/2020 5:36:06 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Sites and Locations for ACTIV-2

Thanks, Ashley!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] <[b6]>
Sent: Monday, August 31, 2020 1:34 PM
To: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Sites and Locations for ACTIV-2

Hi Stacey,

Yes, that's fine we just need to ensure we have the names of the institutions and their locations – thank you!
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, August 31, 2020 1:33 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Sites and Locations for ACTIV-2

Hi Ashley,

I will reach out to the team. Does it have to be in this template? It is likely the team already has a list they can send me, but not in this format, which would be less work for them and get you what you need faster. Would that be okay?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 1:25 PM
To: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Sites and Locations for ACTIV-2

Hi Stacey and David,

We are working to get additional assistance with space/mobile units for the ACTIV outpatient trials. In an effort to match locations of the mobile units we need the list of institutional sites and locations for ACTIV-2.

Attached is a template, Stacey do you have the contacts that can help provide us with the list? Would they be able to gather this information by COB today?

Thanks,
Ashley

From: George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGEJIL]
Sent: 8/25/2020 4:22:05 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks! Looks to me like this has EXACTLY what I need. Sorry to make you do this. Should have been easier... Certainly was in FC's head. 😊

From: Parker, Ashley (NIH/OD) [E] [b6] v>
Sent: Tuesday, August 25, 2020 10:30 AM
To: George, Jill (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6] v>
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks, Jill.

Attached is the example of what FC is asking regarding the separation of the (combination remdesivir + mAbs) and (combination remdesivir + IVIG).

I hope this makes sense.

Thanks,
Ashley

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 3:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Good morning!

I've added the two clinical trial hyperlinks in this version. (They embedded just fine in your email Lauren 😊. Your toddler didn't eat your homework, and I'm sure is pretty darn cute even when driving you crazy.) If they need to be swapped out, no problem.

"CTL+Click to follow link" disappears when viewed as a show.

Okie dokie. This old lady got restless and came downstairs for a bit. But it's time to head back up! Hope you both are sleeping soundly —and that I return to slumberland soon.

Best,
Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 24, 2020 9:51 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: Re: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

APAR0000000776

Thanks, Lauren!

Ashley Parker, Ph.D.

Office of the Director | National Institutes of Health

Tel [b6]

On Aug 24, 2020, at 9:14 PM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Sounds good. And sorry for the delay...my toddler was in meltdown mode tonight so I didn't get a chance to review the revised draft until after he was asleep!

I thought I included the CT hyperlinks in my email below but they might not have copied correctly (just double check to make sure these are the trials you had in mind):

AZ: NCT04516746

<https://clinicaltrials.gov/ct2/show/NCT04516746?term=NCT04516746&draw=2&rank=1>

Janssen: NCT04505722

<https://clinicaltrials.gov/ct2/show/NCT04505722?term=NCT04505722&draw=2&rank=1>

Thanks,

Lauren

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Sent: Monday, August 24, 2020 9:02 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: Re: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks, Lauren. I already sent a revised draft to FC but we still have time for edits.

I don't think the A's should have a click link but I defer to Jill on this.

If you have the links to the NCT's for the vaccine trials please send them so we can link to those. I didn't think Novavax was using the harmonized vaccine protocol but we should ask Mike Santos and find out if we need to include this one.

Thanks,
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Thanks,

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Thanks!!

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Hi Jill and Lauren,

Please see attached edits. Let me know what you think.

Thanks,
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Cc: Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E]
 [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
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Sent: 8/24/2020 6:48:51 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Got it. I'll fix and resend!

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Sent: Monday, August 24, 2020 2:37 PM
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Sent: 8/24/2020 6:42:42 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE
Attachments: DRAFT NIH_ACTIV Checkerboard_8.24.20_PM.pptx

Hi Ashley,

I hope I've accomplished what you wanted. After our phone call, I've brought the number of colors down to 3, as per FC's thoughts. I think it works. Let me know if you'd like any further changes before it gets shared more widely.

There's a lot going on with this, so any help with proofing my work (I think I've done okay) would be greatly appreciated!

Best,
Jill

From: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Sent: Monday, August 24, 2020 10:07 AM
To: George, Jill (NIH/OD) [E] [REDACTED] b6
Cc: Brodd, Lauren (NIH/OD) [E] [REDACTED] b6
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From: Wholley, David (FNIH) [T] [REDACTED] b6
Sent: Monday, August 24, 2020 7:45 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 Parker, Ashley (NIH/OD) [E] [REDACTED] b6

Cc: Freire, Maria (FNIH) [T] { b6 }; Austin, Christopher (NIH/NCATS) [E] { b6 } Lane, Cliff (NIH/NIAID) [E] { b6 }; Anderson, James (NIH/OD) [E] { b6 } Tabak, Lawrence (NIH/OD) [E] { b6 }

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Sent: 8/25/2020 5:55:28 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
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Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hopefully this will be easy! Trying now...

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 1:50 PM
To: George, Jill (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill,

I do not have a preference here but I am inclined to keep them in the order requested to avoid having to go back and make changes again. Can we please list the antivirals + mAbs first?

Thanks,
Ashley

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 1:40 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Here you go! The rows are not in the order you had them, but I think what I've done here makes sense. If I need to change the order or make any changes, just ask!

Thanks,
Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 10:30 AM
To: George, Jill (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks, Jill.

Attached is the example of what FC is asking regarding the separation of the (combination remdesivir + mAbs) and (combination remdesivir + IVIG).

I hope this makes sense.

Thanks,
Ashley

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 3:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Good morning!

I've added the two clinical trial hyperlinks in this version. (They embedded just fine in your email Lauren 😊. Your toddler didn't eat your homework, and I'm sure is pretty darn cute even when driving you crazy.) If they need to be swapped out, no problem.

"CTL+Click to follow link" disappears when viewed as a show.

Okie dokie. This old lady got restless and came downstairs for a bit. But it's time to head back up! Hope you both are sleeping soundly —and that I return to slumberland soon.

Best,
Jill

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Thanks, Lauren!

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

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Thanks!!

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Sent: 8/12/2020 6:12:21 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: ACTIV Daily Update 20200812.pptx

Got it!

Yes, the color code would be helpful, especially for the website since it won't go to the other slides.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 2:03 PM
To: George, Jill (NIH/OD) [E] [b6]
Subject: FW: ACTIV Daily Update 20200812.pptx

FYI – so we remember.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 8:55 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

I think you'd need to change the title from "ACTIV" on the first slide as we discussed, and a key to explain the colors would be good, but agree with Jim this is a great summary.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 8:28 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Please see the attached working draft of the ACTIV grid.

Thanks,
Ashley

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Sent: Wednesday, August 12, 2020 7:17 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: ACTIV Daily Update 20200812.pptx

For this morning's war room, Wednesday August 12. N.B. Maria may not be able to join.

APAR0000000847

From: Elsaid, Olivia [oelsaid@deloitte.com]
Sent: 8/13/2020 7:31:36 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ACTIV EC Pre-call

No problem, appreciate you double-checking Ashley 😊

Olivia Elsaid

Deloitte Consulting LLP

Tel/Direct: +1 617 437 3197 | Mobile: [b6]

www.deloitte.com

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 13, 2020 3:28 PM
To: Wholley, David (FNIH) [T] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>
Subject: [EXT] RE: ACTIV EC Pre-call

OK. Sorry Olivia and David – the launch of these trials are a moving target and constantly changing.

David – I know the press briefings for ACTIV-4 is scheduled for 8/27 based on the note from Renate and we had this as the launch date for hospitalized patients, however since NHLBI has confirmed those dates, I guess it's safe to leave them. I did write a note to Amy to ask for confirmation given this is going to the Secretary.

Thanks so much,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, August 13, 2020 3:19 PM
To: Elsaid, Olivia <oelsaid@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV EC Pre-call

Let me reforward the note from Amy Patterson.

From: Elsaid, Olivia <oelsaid@deloitte.com>
Sent: Thursday, August 13, 2020 3:07 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: ACTIV EC Pre-call

Hi Ashley,

The latest information we received from Andrei is that ACTIV-4 hospitalized is expected launch the week of August 17, pre-hospitalized the week of August 24 and post-hospitalized the first week of September. That's what I have reflected in the milestone slide below, but if you have heard more recent information that says August 27 then I'm happy to adjust this. I'm attaching the latest email chain on this topic that I have, but let me know if you think it should still be adjusted!

ACTIV Milestones



Olivia Elsaid

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From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Thursday, August 13, 2020 2:53 PM

To: Elsaid, Olivia <oesaid@deloitte.com>; Wholley, David (FNIH) [T] [b6]

Subject: [EXT] RE: ACTIV EC Pre-call

Hi Olivia,

I am looking at the timeline for the ACTIV-4 hospitalized trial – we have this down to launch on 8/27. I'm not sure about the pre-hospitalized but I can ask Amy.

I think we need reflect the later launch date on the slide.

Thanks,
Ashley

From: Elsaid, Olivia <oesaid@deloitte.com>

Sent: Thursday, August 13, 2020 10:45 AM

To: Wholley, David (FNIH) [T] [b6] Parker, Ashley (NIH/OD) [E] [b6]

Subject: RE: ACTIV EC Pre-call

That's a good point, David! I've updated those accordingly to move the timeline out to the week of September 13 to avoid any confusion and matched the dates to the statuses we show for each of the ACTIV trials on another slide. Please note that for the ACTIV-4 post-hospitalized cohort, the latest date I have for activation is the first of week of September from the exchange with Andrei, but please let me know if you've heard any new information and I can update that.

Additionally, I added ACTIV-5 (BET) to this slide since we decided to move forward with this naming in the rest of the Tx Clinical section. Please let me know if you have any questions of changes based on the attached.

Thank you!
Olivia

Olivia Elsaid

Deloitte Consulting LLP

Tel/Direct: +1 617 437 3197 | Mobile:

b6

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From: Wholley, David (FNIH) [T] b6 >

Sent: Thursday, August 13, 2020 9:50 AM

To: Elsaid, Olivia <oeelsaid@deloitte.com>; Parker, Ashley (NIH/OD) [E] b6

Subject: [EXT] RE: ACTIV EC Pre-call

The third slide gives the impression that ACTIV-1 and the third arm of ACTIV-4 will both begin by the end of August, but both of these will occur sometime between September 1-15 from what I have heard. I would find a way to show that on the slides: either extend the timeline through Sept 15 or put an arrow pointing right next to each of the existing diamonds for those trials, with the relevant projected date below in italics. Thanks, David

From: Elsaid, Olivia <oeelsaid@deloitte.com>

Sent: Thursday, August 13, 2020 9:34 AM

To: Parker, Ashley (NIH/OD) [E] b6; Wholley, David (FNIH) [T] b6

Subject: RE: ACTIV EC Pre-call

Hi Ashley,

Please find attached a slightly updated version of the three slides. David – let me know if you see any further changes to these.

Thank you!
Olivia

Olivia Elsaid

Deloitte Consulting LLP

Tel/Direct: +1 617 437 3197 | Mobile:

b6

www.deloitte.com

From: Parker, Ashley (NIH/OD) [E] b6

Sent: Thursday, August 13, 2020 8:57 AM

To: Wholley, David (FNIH) [T] b6; Elsaid, Olivia <oeelsaid@deloitte.com>

Subject: [EXT] RE: ACTIV EC Pre-call

Good morning David and Olivia,

We will share the attendee, agenda, and milestones slide for Dr. Collins' meeting with the Secretary – I just wanted to confirm that we have no additional changes on those slides.

Thank you,
Ashley

Attendees for ACTIV Executive Committee Meeting

ACTIV EXECUTIVE COMMITTEE		ACTIV WORKING GROUP CO-CHAIRS		NON-PROFIT
 Francis Collins*		 Christine Colvis		 Maria Freire
 Paul Stoffels*		 Mike Kurilla		
 Anthony Fauci		 Sarah Read		
 Gary Gibbons		 [Doug Lowy]		
 Gary Disbrow		 Eric Hughes		
 Janet Woodcock		 John Young		
 Peter Marks		 Betty Desrosiers		
 William Pan		 [Kathrin Jansen]		
 Mikael Dolsten				
 Andrew Plump				

PROGRAM MANAGEMENT

David Wholley
Joe Menetiki
Stacey Adam
Karen Tountas
Michael Santos
Stephanie James
Margaret Anderson
Nina Gonzalez
Benjamin Stratton
Olivia Elsaid
Jonathan Wachel
Rosa Alvarez
Helen Chen
Brett Tolman

 FNIH Notes: D Denotes a leader not able to attend; * Denotes ACTIV Executive Committee Co-Chair

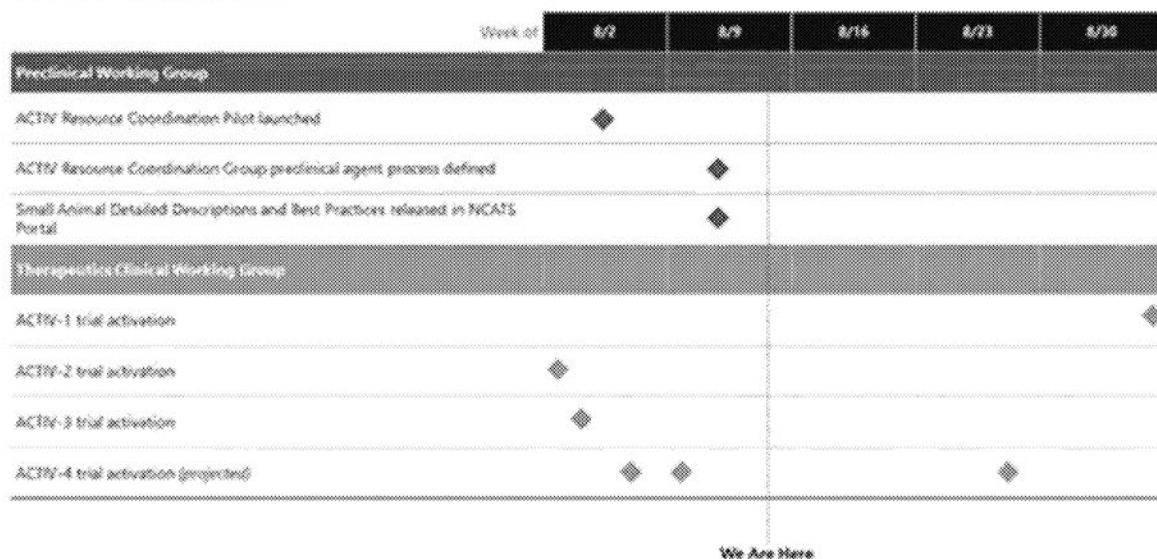
Confidential and Pre-decisional

Agenda

TIME	TOPIC	SPEAKER(S)
12:00 – 12:05 PM 5 mins	Introduction and General Updates on ACTIV	Francis Collins (NIH) Paul Stoffels (J&J)
12:05 – 12:10 PM 5 mins	Progress on Action Items from Previous Meetings	David Wholley (FNIH)
12:10 – 12:30 PM 20 mins	Working Group Updates and Q&A	ACTIV Preclinical Christine Colvis (NCATS), John Young (Roche)
12:30 – 12:50 PM 20 mins		ACTIV Therapeutics Clinical Sarah Read (NIAID), Eric Hughes (Novartis)
12:50 – 1:00 PM 10 mins	Milestones and Discussion	Francis Collins (NIH) David Wholley (FNIH)

 FNIH

ACTIV Milestones



From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 11:54 AM
To: Melencio, Cheryl (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Margaret <marganderson@deloitte.com>; Chen, Helen <qingchen@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; James, Stephanie (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Stratton, Benjamin <bstratton@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Hawk, Harrison <hhawk@deloitte.com>; Colvis, Christine (NIH/NCATS) [E] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]
Subject: RE: ACTIV EC Pre-call
Importance: High

Please see attached the proposed slides and attendee list for our pre-call.

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Tuesday, July 21, 2020 2:04 PM
To: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Benjamin; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Hawk, Harrison; Colvis, Christine (NIH/NCATS) [E]
Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]
Subject: ACTIV EC Pre-call
When: Wednesday, August 12, 2020 12:00 PM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: see webex below

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From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 8/5/2020 4:42:17 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]
Subject: Re: call with Moncef

Those are very good points.

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Wednesday, August 5, 2020 at 12:03:16 PM
To: "Freire, Maria (FNIH) [T]" [b6], "Wholley, David (FNIH) [T]" [b6], "Menetski, Joseph (FNIH) [T]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Fauci, Anthony (NIH/NIAID) [E]" [b6]
Subject: call with Moncef

Hi all,

I spoke with Moncef about the idea of the ACTIV Vaccines WG convening occasional meetings of the vaccine companies to compare notes on progress. He said the conversation might be interesting – but the content would be immediately share price sensitive and it would be very hard to keep it from leaking. Even such things as number of recruits and their demographics could be seen as tipping the balance towards early outcome, and that would ignite interest on Wall Street.

For that reason, he doesn't think this broader discussion could work. He isn't even sure a very tightly knit group could keep a lid on the information.

I'll speak with Dolsten this afternoon and see what he thinks. I'll also press him again about having DSMB chairs share safety data – though Moncef thinks it's the lipid in the mRNA vaccines that will define the safety profile, not the mRNA.

FC

APAR0000000876

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 8/12/2020 10:38:59 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: ACTIV Daily Update 20200812.pptx

Sure, just answering Ashley's question.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 2:57 PM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

That was the tentative idea, but we need to discuss again in tomorrow's War Room.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 2:29 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Freire, Maria (FNIH) [T] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Well, we have not decided exactly, but I thought we were entertaining ACTIV for trials 1-4 and probably 5 (BET), "ACTIV-Associated Trials" for IVIG and Conv. Plasma efforts, and NIH Covid Trials for everything else.h

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 2:17 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Hi David,

Sorry I missed this. What did we decide? ACTIV and NIH COVID Treatment Trials? ACTIV and ACTIV-Like Trials?

I will rename the BET trial as (ACTIV-5), include the IVIG (ACTIV-like 6 or ACTIV-6 study?), and rename the CP trials (ACTIV-like 7a; 7b; etc.?)

Thank you,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 8:55 AM

To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

I think you'd need to change the title from "ACTIV" on the first slide as we discussed, and a key to explain the colors would be good, but agree with Jim this is a great summary.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 8:28 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Please see the attached working draft of the ACTIV grid.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 7:17 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: ACTIV Daily Update 20200812.pptx

For this morning's war room, Wednesday August 12. N.B. Maria may not be able to join.

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 8/12/2020 12:47:59 PM
To: Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]
Subject: Re: ACTIV Daily Update 20200812.pptx

I agree Jim; it is very helpful and would be a very useful communication tool. This was put together because it was hard for us (well, me anyway) who are in the thick of things, to keep everything straight. M.

On Aug 12, 2020, at 8:41 AM, Anderson, James (NIH/OD) [E] <b6> wrote:

This effectively displays the global strategy of ACTIV. Why not make a public version for the taxpayers who are paying for ACTIV, for those being effected by the virus and those desperate enough to seek their facts on social media? I find this reassuring. Someone in the government is thinking clearly and strategically.

Jim

From: Parker, Ashley (NIH/OD) [E] <b6>
Sent: Wednesday, August 12, 2020 8:28 AM
To: Wholley, David (FNIH) [T] <b6> Collins, Francis (NIH/OD) [E] <b6>; Tabak, Lawrence (NIH/OD) [E] <b6>; Lane, Cliff (NIH/NIAID) [E] <b6>; Freire, Maria (FNIH) [T] <b6>; Austin, Christopher (NIH/NCATS) [E] <b6>; Anderson, James (NIH/OD) [E] <b6>
Subject: RE: ACTIV Daily Update 20200812.pptx

Please see the attached working draft of the ACTIV grid.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <b6>
Sent: Wednesday, August 12, 2020 7:17 AM
To: Collins, Francis (NIH/OD) [E] <b6> Tabak, Lawrence (NIH/OD) [E] <b6>; Lane, Cliff (NIH/NIAID) [E] <b6>; Freire, Maria (FNIH) [T] <b6> Austin, Christopher (NIH/NCATS) [E] <b6> Parker, Ashley (NIH/OD) [E] <b6>; Anderson, James (NIH/OD) [E] <b6>
Subject: ACTIV Daily Update 20200812.pptx

For this morning's war room, Wednesday August 12. N.B. Maria may not be able to join.

APAR0000000900

From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 7/23/2020 3:48:34 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cabcd42247548e596778304f781f-austinc]
Subject: RE: ACTIV Daily Update July 23
Attachments: ACTIV Daily Update 20200723.pptx

Slides for the meeting.

Sorry

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Wednesday, July 22, 2020 7:17 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: ACTIV Daily Update July 22

Slides for today's war room call, Wednesday July 22.

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, July 16, 2020 10:31 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]
Subject: ACTIV Daily Update 20200716.pptx

Slides for today's war room call, Thursday July 16. Joe Menetski will be joining us.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 7/14/2020 5:35:17 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user0fe7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4b79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
Subject: RE: Pre-Call: ACTIV EC & WG Chairs Meeting
Attachments: 7.15 ACTIV Executive Committee Meeting 20200714 v1_.pptx

For our call at 1:45

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6]

Sent: Monday, June 8, 2020 12:01 PM

To: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; oelsaid; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]

Cc: McManus, Ayanna (NIH/OD) [E]; Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

Subject: Pre-Call: ACTIV EC & WG Chairs Meeting

When: Tuesday, July 14, 2020 1:45 PM-2:15 PM (UTC-05:00) Eastern Time (US & Canada).

Where: see webex below

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From: Menetski, Joseph (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5001AF52DC4A427EA3D34F1E072F8CB7-MENETSKIJP]
Sent: 7/21/2020 11:27:33 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: ACTIV Daily Update July 21
Attachments: ACTIV Daily Update 20200721.pptx

Slides for today's war room call, Tuesday July 21.

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, July 16, 2020 10:31 AM
To: Collins, Francis (NIH/OD) [E] [b6] Tabak, Lawrence (NIH/OD) [E] [b6]
Freire, Maria (FNIH) [T] [b6] Lane, Cliff (NIH/NIAID) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6] Austin, Christopher (NIH/NCATS) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]
Subject: ACTIV Daily Update 20200716.pptx

Slides for today's war room call, Thursday July 16. Joe Menetski will be joining us.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/29/2020 7:57:45 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Alvarez, Rosa [rosalvarez@deloitte.com]; Anderson, Margaret [marganderson@deloitte.com]; Chen, Helen [qingchen@deloitte.com]; oelsaid [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user0fe7bd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]; James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Stratton, Ben [bstratton@deloitte.com]; Tolman, Brett [btolman@deloitte.com]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Wachtel, Jonathan [jwachtel@deloitte.com]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Simon, Dina (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e02345fa5d1d4d7eaf4e0f3da58bc1ac-simondm]
Subject: RE: Pre-call ACTIV Leadership Call
Attachments: ACTIV 7.1 Leadership Team Meeting 20200629 v3.pptx

Here are the slides for review at 4

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6]

Sent: Monday, June 8, 2020 11:04 AM

To: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]

Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

Subject: Pre-call ACTIV Leadership Call

When: Monday, June 29, 2020 4:00 PM-4:45 PM (UTC-05:00) Eastern Time (US & Canada).

Where: see webex below

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From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 6/25/2020 10:51:07 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: ACTIV-1 in trouble again?

Let me see how she responds to my message and my phone invitation at the end of it.

FC

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Thursday, June 25, 2020 6:38 PM
To: Austin, Christopher (NIH/NCATS) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: Re: ACTIV-1 in trouble again?

Francis,
Do you want to speak to Janet directly about this before having this larger group engage?
Larry

From: "Austin, Christopher (NIH/NCATS) [E]" [b6]
Date: Thursday, June 25, 2020 at 6:35 PM
To: Francis Collins [b6], "Wholley, David (FNIH) [T]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Freire, Maria (FNIH) [T]" [b6]
Subject: RE: ACTIV-1 in trouble again?

Thanks Francis. I (and Mike Kurilla) told her the dynamics with DAIT that in our minds mitigated the importance of their objections, that we were ready to go with the CRO/Duke model (which in fact we are), and that the Therapeutics WG had decided the dex study should not change the protocol. She doesn't agree with that assessment, and wants to revisit with all those involved. The group I had in mind is

Me
Mike Kurilla
Sam Bozzette

Jane Atkinson
Sarah Read
Eric Hughes
Stacey Adam
Cliff Lane

Please add names; I'd like to get this scheduled tomorrow.

Chris

From: Collins, Francis (NIH/OD) [E] <[b6]>
Sent: Thursday, June 25, 2020 6:25 PM
To: Wholley, David (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] <[b6]>; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: ACTIV-1 in trouble again?

Hi all,

I am supremely frustrated about the latest round of second-guessing about immunomodulators and ACTIV-1. Just sent the message below to Janet. I just don't get this.

Francis

From: Collins, Francis (NIH/OD) [E]
Sent: Thursday, June 25, 2020 6:22 PM
To: Woodcock, Janet [b6]
Subject: RE: got \$\$ for immunomodulator study

Hi Janet,

I just got a message from Chris Austin (his summary is below, please tell me if this is not accurate). Now I am really confused about ACTIV-1 (the three immunomodulators). When Moncef was skeptical about the scientific basis for the choice of these three agents (on May 29, almost four weeks ago), we went through that in considerable detail, and he eventually agreed (or at least didn't object). You sent me a note a week ago (below) saying that the \$\$ had been allocated. So we moved ahead.

But now? I was disappointed that DAIT was not enthusiastic about the trial, but they are traditionally a rather academic group and didn't like the idea of having to do things this quickly and take risks that it might not work. So we moved quickly to identify a CRO model through NCATS and Duke, and that looked like the right way to get this done. ACTIV-1 has already taken longer to launch this than it should, so we were highly motivated to get it going. The Therapeutics WG already looked at the protocol, and my understanding is that the dex study did not change their view on how the study should be conducted (though I don't have the details on this).

I fear the companies are going to walk pretty soon if this doesn't get underway. The ACTIV Therapeutics WG will be deeply demoralized if this all blows up. How long will this re-re-evaluation likely take?

Sorry, I guess my frustration is showing a bit here. Glad to talk by phone if that would help.

b6

Francis

From Chris Austin:

ACTIV-1: Janet is not comfortable with the protocol as is, given the RECOVERY dex data (see <https://www.medrxiv.org/content/10.1101/2020.06.22.20137273v1> just out), the many other immunomodulators she knows are being tested by companies, and objections she heard DAIT had. She wants to see the original evaluation that ACTIV did to select the three compounds, and the written comments from DAIT. She thinks the protocol will likely need to be re-written to account for dex; she brought up again the concept of the "screening trial." To decide what to do, she wants a meeting with her extended group and NCATS

From: Woodcock, Janet

b6

Sent: Thursday, June 18, 2020 4:41 PM

To: Collins, Francis (NIH/OD) [E]

b6

Subject: got \$\$ for immunomodulator study

But they are not ready yet. Will provide when they are ready. jw

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/21/2020 7:41:06 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: FW: Urgent Asks about ACTIV mAb Protocols/Studies
Attachments: 5401 Protocol Synopsis 051920v3.docx

Hi Larry:

As we just discussed on the daily update call. Please treat with discretion. Thanks

From: Bugin, Kevin <[REDACTED] b6 [REDACTED]>
Sent: Thursday, May 21, 2020 2:18 PM
To: Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED]; Adam, Stacey (FNIH) [T] [REDACTED] b6 [REDACTED]
Cc: Woodcock, Janet (FDA/CDER) [REDACTED] b6 [REDACTED]
Subject: Urgent Asks about ACTIV mAb Protocols/Studies
Importance: High

Hi David and Stacey,

I hope your week is going well. I'm definitely seeing a lot of activity! Sadly, we might need to add to your load.

Dr. Woodcock has just been asked to provide near immediate input (i.e., by this weekend) into the development of a budget for the Therapeutics activities that are part of Operation Warp Speed. As you know, we intend to collaborate with you and ACTIV for the two mAb master protocols for outpatient and inpatient. While ACTIV and NIH will likely fund much of that work, we expect Operation Warp Speed via BARDA will help augment and act as a force multiplier related to the CRO and networks/sites. While we only have a protocol synopsis at this point for outpatient we believe we can use that to some extent to base estimates for size/complexity of the two studies which we can use to estimate CRO costs. In addition, any information that has started to come through about the networks/sites that ACTIV wants to leverage—that I understand Mike K's group is pulling together—will be very helpful. Depending on where we are targeting sites, we can check BARDA's portfolio and our Clinical Trial Data Lake to identify potential concerning overlaps and gaps. Not to second guess anything, but to help us guesstimate additional CRO/Site/Network demands.

All this to say, **can you confirm that the attached is the most current outpatient synopsis? Are you OK if we use this to inform BARDA's development of an RFI to CROs to get some quick bids/estimates?** Also, **do you know the timeline for Mike's working group for updating their inventory?** If this isn't this week, no problem. We're not entirely sure how much that will inform budget ask at this point since there is much to still work through. But, wanted to ask.

Thanks,
Kevin

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 10/9/2020 10:12:52 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: Daily ACTIV Call

Thank you Ashley!

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Friday, October 9, 2020 at 3:42:56 AM
To: "Freire, Maria (FNIH) [T]" [b6]
Subject: Fwd: Daily ACTIV Call

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

Begin forwarded message:

From: "Menetski, Joseph (FNIH) [T]" [b6]
Date: October 8, 2020 at 11:00:39 PM EDT
To: "Melencio, Cheryl (FNIH) [T]" [b6], "Collins, Francis (NIH/OD) [E]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6]
Subject: RE: Daily ACTIV Call

Dear All,

Here are ACTIV update slides for discussion at the morning meeting.

Best,

Joe

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, October 2, 2020 1:00 PM
To: Melencio, Cheryl (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Lane, Cliff (NIH/NIAID) [E]; Austin, Christopher (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Anderson, James (NIH/OD) [E]; Menetski, Joseph (FNIH) [T]; Wholley, David (FNIH) [T]
Cc: Wood, Gretchen (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Lagos, Enrique (NIH/NCATS) [E]; Hughes, Karen (NIH/OD) [E]; Sepulveda, Dorina (FNIH) [T]
Subject: Daily ACTIV Call
When: Friday, October 9, 2020 8:00 AM-8:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: Dial-in: [b6] Passcode: [b6]

Extending to end of November

Dial-in:

Passcode:

Dr. Tabak as Leader:

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 9/29/2020 12:07:25 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

Thanks, Ashley!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, September 28, 2020 8:01 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Re: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

Hi Stacey,

I suspect Francis is catching up on emails and will hopefully give the green light on the ACTIV-2 letter at some point tonight.

Thanks,
Ashley

On Sep 28, 2020, at 7:10 PM, Adam, Stacey (FNIH) [T] [b6] wrote:

Hi Ashley,

I understand. It was my understanding that the team now wanted to be able to tailor it to each site, and wanted confirmation that that is okay. However, I am checking.

Can I take the below as approval for the ACTIV-2 Encouragement Letter?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, September 28, 2020 6:01 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

Hi Stacey,

The letter tailored for the specific PI is for ACTIV-2, right? If so, that one seemed fine. We also received a draft general letter for ACTIV-3 which looks very similar to the original ACTIV-3 letter – this is the letter I was flagging.

Happy to chat if needed.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] <b6>
Sent: Monday, September 28, 2020 5:48 PM
To: Parker, Ashley (NIH/OD) [E] <b6> Wholley, David (FNIH) [T]
<b6> Collins, Francis (NIH/OD) [E] <b6>
Cc: Wood, Gretchen (NIH/OD) [E] <b6>
Subject: RE: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

Hi Ashley,

The letter I received from the team was tailored to a particular PI. I had assumed this team had done that which is why they wanted the generalized one. I can go back and ask if it is helpful.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: <b6> Mobile: <b6>

From: Parker, Ashley (NIH/OD) [E] <b6>
Sent: Monday, September 28, 2020 5:47 PM
To: Wholley, David (FNIH) [T] <b6>; Collins, Francis (NIH/OD) [E] <b6>
Cc: Wood, Gretchen (NIH/OD) [E] <b6>; Adam, Stacey (FNIH) [T]
Subject: RE: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

I defer to Francis but seems the existing ACTIV-3 letter could be forwarded to new sites as they launch considering it practically reads the same and it can continue to be used (there was no date). Just my observation but I defer to FC's preference here.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <b6>
Sent: Monday, September 28, 2020 5:22 PM
To: Parker, Ashley (NIH/OD) [E] <b6>; Collins, Francis (NIH/OD) [E]
<b6>

Cc: Wood, Gretchen (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

In truth it is not all that different. The first letter was sent only to those sites that were open at the time. My understanding is that this second letter, because it is not pdf'd, is a standing letter that allows the NIH clinical teams to send them to the new sites—those that have opened since the last letter and those that will be opened continually from now on. If there is still a problem with this let me and Stacey know and we will go back to the teams.

Thanks, David

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, September 28, 2020 5:14 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]
Subject: Re: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

Hi David,

I understand the draft ACTIV-2 letter is congratulating the sites for enrolling their first patient but how is the draft ACTIV-3 letter any different from the previous letter signed by FC and JW that presumably went out to the ACTIV-3 sites? I've attached the previous ACTIV-3 letter for reference.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, September 28, 2020 1:38 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]
Subject: FW: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

Hi Francis:

Please see attached for your review and approval. Copying Ashley. Please let me know what else you might need from us. Thanks very much for your help.

David

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, September 28, 2020 1:27 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3

Hi David,

Please find attached the DRAFT Site Lead and Site PI Encouragement Letters for ACTIV-2 and ACTIV-3 for review by NIH OD and FC. The idea would be that these drafts would be populated by the study teams and sent on behalf of FC and JW.

Would you mind passing these along, or should I work with Ashley Parker?

Thanks,

Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: [b6] Mobile: [b6]

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<image001.jpg> <image002.jpg> <image003.jpg> <image004.jpg>

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

<image005.png>

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 9/29/2020 9:20:55 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Thanks, Ashley!

Very much appreciated!

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, September 29, 2020 5:14 PM
To: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi Stacey,

The Rise Above COVID link is now live <https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials>.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, September 25, 2020 5:17 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Thanks, Ashley,

This is great! Go with Rise Above COVID.

And thanks for letting me know where the clinicaltrial.gov links are. I bet the teams, as I were just not looking for it to be there.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, September 25, 2020 5:13 PM
To: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi Stacey,

The CT.gov links to the trials listed below (ACTIV-2,3, 4a, 4b) are already available on the Therapeutics page under more information – see “Clinical Trial Record” for each trial that has launched <https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials>.

We can add the link to the ACTIV-2 website under the ACTIV-2 trial – OK to list as Rise Above COVID Campaign? I’m also happy to work with OCPL to add additional links once they are ready.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, September 25, 2020 4:49 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi Ashley,

The team would like the ACTIV-2 website:
<https://www.activ-2.org/en>

They would like the Clinicaltrials.gov links added:

ACTIV-1: TBD

ACTIV-2: <https://clinicaltrials.gov/ct2/show/NCT04518410?term=ACTIV&cond=Covid19&draw=2&rank=3>

ACTIV-3: <https://clinicaltrials.gov/ct2/show/NCT04501978?term=ACTIV&cond=Covid19&draw=2&rank=2>

ACTIV-4a: <https://clinicaltrials.gov/ct2/show/NCT04505774?term=ACTIV&cond=Covid19&draw=2&rank=4>

ACTIV-4b: <https://clinicaltrials.gov/ct2/show/NCT04498273?term=ACTIV&cond=Covid19&draw=2&rank=5>

ACTIV-4c: TBD

ACTIV-5: TBD

In addition, there will be ACTIV websites built for ACTIV-1 and possibly ACTIV-4 that will need to be added later.

The teams would like them added to the Therapeutics page where the trials and the press releases are listed.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, September 25, 2020 8:52 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Thanks, David for looping me in – happy to help.

Hi Stacey – can you please send me the specific changes and links that should be added to the therapeutics page? Also to be clear, these changes are preferred to the therapeutics page versus the therapeutics clinical WG page?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, September 25, 2020 8:35 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]
Subject: FW: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Ashley, as promised here is the issue we need addressed with Renate. Thank you very much for taking this on. David

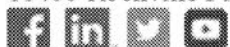
From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, September 24, 2020 5:55 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi David,

Again on the ACTIV Cross Trial Operations call, it was raised by the teams if we can get the specific trial website links put up on the main ACTIV Therapeutics webpage? Shall we follow up with NIH OD Comms team again to see if there was a ruling on this?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
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fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 10/19/2020 5:50:22 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Permission to add you to ACTIV Working Group Webpage

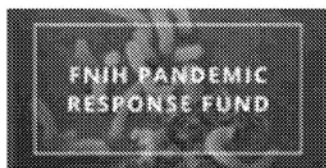
Same to you!

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

b6
fnih.org

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From: Parker, Ashley (NIH/OD) [E] **b6**
Sent: Monday, October 19, 2020 1:50 PM
To: Melencio, Cheryl (FNIH) [T] **b6**; Brodd, Lauren (NIH/OD) [E] **b6**
Subject: RE: Permission to add you to ACTIV Working Group Webpage

Thanks, Cheryl! Happy Monday! ☺

Ashley

From: Melencio, Cheryl (FNIH) [T] **b6**
Sent: Monday, October 19, 2020 9:56 AM
To: Brodd, Lauren (NIH/OD) [E] **b6**; Parker, Ashley (NIH/OD) [E] **b6**
Subject: FW: Permission to add you to ACTIV Working Group Webpage

Here is another person to add to the webpage for the Therapeutics – Pre-clinical Working Group. I have also updated the ACTIV Roster, which is attached.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

b6
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APAR0000022225



From: Mason, Stephen [b6]
Sent: Friday, October 16, 2020 5:36 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: Permission to add you to ACTIV Working Group Webpage

Hi Cheryl,
Yes, please.

Stephen Mason, Ph.D.
Research Associate & Viral Drug Discovery Fellow
Pfizer Inc.

Best, Steve

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, October 16, 2020 4:32 PM
To: Mason, Stephen [b6]
Subject: [EXTERNAL] Permission to add you to ACTIV Working Group Webpage

Dear Dr. Mason:

I am writing to get your permission to add you to the ACTIV Website on the working group page for the Therapeutics – Pre-Clinical Working Group page. If so, please confirm that the following is correct:

Stephen Mason (NOTE: please provide your degrees M.D., Ph.D., etc.)
Research Associate & Viral Drug Discovery Fellow
Pfizer Inc

Thank you

Cheryl
Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 10/16/2020 2:52:47 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv15Oct2020

Sure will do.

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Sent: Friday, October 16, 2020 10:51 AM
To: Brodd, Lauren (NIH/OD) [E] [REDACTED] b6
Subject: RE: Emailing: Master and WG Email List for ACTIV rv15Oct2020

Ok, could you update our version and send to Cheryl whenever you have a chance? This is not urgent but I'm thinking she forget we updated the spreadsheet -- I do not recall that she acknowledged receiving it although you shared it.

-----Original Message-----

From: Brodd, Lauren (NIH/OD) [E] [REDACTED] b6
Sent: Friday, October 16, 2020 10:48 AM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Subject: RE: Emailing: Master and WG Email List for ACTIV rv15Oct2020

So Cheryl's file from yesterday is attached, but it looks like she made the addition to her version of the file, rather than using ours (most recent one we had sent is attached). Maybe there is a reason she prefers to use hers versus the one we created. I checked hers, and along with the addition from yesterday, she does have the additions we had added last time (Isis Kanevsky and Sheri Hild).

-----Original Message-----

From: Brodd, Lauren (NIH/OD) [E]
Sent: Friday, October 16, 2020 8:51 AM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Subject: RE: Emailing: Master and WG Email List for ACTIV rv15Oct2020

I'll double check to make sure!

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Sent: Thursday, October 15, 2020 5:12 PM
To: Brodd, Lauren (NIH/OD) [E] [REDACTED] b6
Subject: FW: Emailing: Master and WG Email List for ACTIV rv15Oct2020

Hopefully she updated the most recent version!

-----Original Message-----

From: Melencio, Cheryl (FNIH) [T] [REDACTED] b6
Sent: Thursday, October 15, 2020 3:20 PM
To: Brodd, Lauren (NIH/OD) [E] [REDACTED] b6; Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>
Subject: Emailing: Master and WG Email List for ACTIV rv15Oct2020

Here is updated spreadsheet
Cheryl

Your message is ready to be sent with the following file or link attachments:

Master and WG Email List for ACTIV rv15Oct2020

Note: To protect against computer viruses, e-mail programs may prevent sending or receiving certain types of file attachments. Check your e-mail security settings to determine how attachments are handled.

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 10/19/2020 5:01:25 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Permission to add you to ACTIV Working Group Webpage

Thanks, Cheryl!

Lauren

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Monday, October 19, 2020 9:56 AM
To: Brodd, Lauren (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Permission to add you to ACTIV Working Group Webpage

Here is another person to add to the webpage for the Therapeutics – Pre-clinical Working Group. I have also updated the ACTIV Roster, which is attached.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

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From: Mason, Stephen [b6]
Sent: Friday, October 16, 2020 5:36 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: RE: Permission to add you to ACTIV Working Group Webpage

Hi Cheryl,
Yes, please.

Stephen Mason, Ph.D.

**Research Associate & Viral Drug Discovery Fellow
Pfizer Inc.**

Best, Steve

APAR0000022236

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Friday, October 16, 2020 4:32 PM
To: Mason, Stephen [b6]
Subject: [EXTERNAL] Permission to add you to ACTIV Working Group Webpage

Dear Dr. Mason:

I am writing to get your permission to add you to the ACTIV Website on the working group page for the Therapeutics – Pre-Clinical Working Group page. If so, please confirm that the following is correct:

Stephen Mason (NOTE: please provide your degrees M.D., Ph.D., etc.)

Research Associate & Viral Drug Discovery Fellow

Pfizer Inc

Thank you

Cheryl
Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]

fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 9/28/2020 12:18:27 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

I was trying to be optimistic, but I agree.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, September 28, 2020 7:50 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

I'm not too confident since the update to the main ACTIV page was supposed to happen last week.

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Sep 28, 2020, at 7:39 AM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Sure will do. They did change the heparin abbreviations but not the main COVID page yet. Hopefully they will do that when they make the change below.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, September 28, 2020 7:34 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Fwd: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi Lauren,

Can you please let me know when this update is on the site include the change needed on the main COVID page?

Thanks,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

Begin forwarded message:

From: "Myles, Renate (NIH/OD) [E]" [b6]
Date: September 25, 2020 at 8:59:06 PM EDT
To: "Parker, Ashley (NIH/OD) [E]" [b6], "Wojtowicz, Emma (NIH/OD) [E]" [b6]

Cc: "Brodd, Lauren (NIH/OD) [E]" [b6]
Subject: Re: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

No problem, Ashley. We'll add it.

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health

[b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, September 25, 2020 5:58 PM
To: Myles, Renate (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi Renate and Emma,

FNIH raised questions about including links on the ACTIV Tx page. I let them know we already have links to [CT.gov](https://www.ct.gov) on the Therapeutics webpage and will add others when they are ready – Stacey will share this information with the Clinical Tx WG.

Whenever you have a chance, can we please add the link to "[Rise Above COVID](#)" under more information for ACTIV-2? We try to limit sending any ACTIV updates to once per week but I wanted to let you know before NIH and FNIH meets again on Monday morning. I completely understand OCPL has a ton of other things to manage!

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, September 25, 2020 5:17 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
[b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Thanks, Ashley,

This is great! Go with Rise Above COVID.

And thanks for letting me know where the clinicaltrials.gov links are. I bet the teams, as I were just not looking for it to be there.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6] >
Sent: Friday, September 25, 2020 5:13 PM
To: Adam, Stacey (FNIH) [T] [b6]; Wholley, David (FNIH) [T]
[b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi Stacey,

The [CT.gov](https://www.ct.gov) links to the trials listed below (ACTIV-2,3, 4a, 4b) are already available on the Therapeutics page under more information – see “Clinical Trial Record” for each trial that has launched <https://www.nih.gov/research-training/medical-research-initiatives/activ/covid-19-therapeutics-prioritized-testing-clinical-trials>.

We can add the link to the ACTIV-2 website under the ACTIV-2 trial – OK to list as Rise Above COVID Campaign? I’m also happy to work with OCPL to add additional links once they are ready.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, September 25, 2020 4:49 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
[b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi Ashley,

The team would like the ACTIV-2 website:
<https://www.activ-2.org/en>

They would like the [Clinicaltrials.gov](https://clinicaltrials.gov) links added:

ACTIV-1: TBD

ACTIV-2:

<https://clinicaltrials.gov/ct2/show/NCT04518410?term=ACTIV&cond=Covid19&draw=2&rank=3>

ACTIV-3:

<https://clinicaltrials.gov/ct2/show/NCT04501978?term=ACTIV&cond=Covid19&draw=2&rank=2>

ACTIV-4a:

<https://clinicaltrials.gov/ct2/show/NCT04505774?term=ACTIV&cond=Covid19&draw=2&rank=4>

ACTIV-4b:

<https://clinicaltrials.gov/ct2/show/NCT04498273?term=ACTIV&cond=Covid19&draw=2&rank=5>

ACTIV-4c: TBD

ACTIV-5: TBD

In addition, there will be ACTIV websites built for ACTIV-1 and possibly ACTIV-4 that will need to be added later.

The teams would like them added to the Therapeutics page where the trials and the press releases are listed.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, September 25, 2020 8:52 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T]
[b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6] <ov>
Subject: RE: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Thanks, David for looping me in – happy to help.

Hi Stacey – can you please send me the specific changes and links that should be added to the therapeutics page? Also to be clear, these changes are preferred to the therapeutics page versus the therapeutics clinical WG page?

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Friday, September 25, 2020 8:35 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]
Subject: FW: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Ashley, as promised here is the issue we need addressed with Renate. Thank you very much for taking this on. David

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Thursday, September 24, 2020 5:55 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: ACTIV Trial Website Links on Main ACTIV Therapeutics Webpage

Hi David,

Again on the ACTIV Cross Trial Operations call, it was raised by the teams if we can get the specific trial website links put up on the main ACTIV Therapeutics webpage? Shall we follow up with NIH OD Comms team again to see if there was a ruling on this?

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: b6 | Mobile: (301) 318-8310

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

<image001.jpg> <image002.jpg> <image003.jpg> <image004.jpg>

Donate to the FNIH's Pandemic Response Fund to combat COVID-19:

fnih.org/pandemic

<image005.png>

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 10/19/2020 12:28:03 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Publication of ACTIV Vaccines vaccine safety journal article on Monday

Thanks for sharing!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, October 19, 2020 8:10 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: FW: Publication of ACTIV Vaccines vaccine safety journal article on Monday

Another item to add to the list we plan to send to OCPL today.

Thanks!
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Sunday, October 18, 2020 11:14 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Santos, Michael (FNIH) [T] [b6]
Subject: Publication of ACTIV Vaccines vaccine safety journal article on Monday

Dear War Room colleagues:

FYI the ACTIV Vaccines Working Group journal article on COVID-19 vaccine safety (specifically vaccine-associated enhanced disease) was accepted on Friday by Science Translational Medicine. A pre-proof version of the article will be made available tomorrow, Monday Oct 19 at 2pm, at this link:
<https://science.sciencemag.org/lookup/doi/10.1126/science.abe0948>. The journal will roll out a press package Monday (more information and contact below). Information concerning the article will be embargoed until the 2PM release.
Thanks, David

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 9/21/2020 3:38:48 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: NIH-ACTIV Clinical Trial Matrix

You deserved a shoutout! 📣

On Sep 21, 2020, at 11:37 AM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Thank you Maria for your kind words this morning! 😊

From: Freire, Maria (FNIH) [T] [b6]
Sent: Friday, September 18, 2020 3:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: NIH-ACTIV Clinical Trial Matrix

Thanks Ashley!

On Sep 18, 2020, at 2:44 PM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Sorry something strange happened – please try this one!

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, September 18, 2020 2:29 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: NIH-ACTIV Clinical Trial Matrix

Good afternoon,

For your awareness, the ACTIV therapeutics clinical WG provided feedback on the clinical trial matrix – attached is the most recent version with revisions including logos to indicate completed trials. We will continue to update as trials continue to launch and complete.

Thanks,
Ashley

<DRAFT ACTIV Checkerboard_9.18.20 updated 2pm.pptx>

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 9/21/2020 11:12:20 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: RESPONSE REQUESTED: Permission to list to you on ACTIV Website

Thanks, Ashley.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Sunday, September 20, 2020 8:24 PM
To: Myles, Renate (NIH/OD) [E] [b6] Wojtowicz, Emma (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Fwd: RESPONSE REQUESTED: Permission to list to you on ACTIV Website

FYI

Begin forwarded message:

From: "Melencio, Cheryl (FNIH) [T]" [b6]
Date: September 19, 2020 at 6:49:09 PM EDT
To: "Brodd, Lauren (NIH/OD) [E]" [b6] >, "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: RESPONSE REQUESTED: Permission to list to you on ACTIV Website

Response from Sheri Hild.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Hild, Sheri (NIH/OD) [E] [b6]
Sent: Friday, September 18, 2020 8:45 PM

APAR0000022324

To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: Re: RESPONSE REQUESTED: Permission to list to you on ACTIV Website

Yes you can list me and the information is correct. Sheri

Sent from my iPhone

On Sep 18, 2020, at 9:21 AM, Melencio, Cheryl (FNIH) [T] [b6] wrote:

Dear Dr. Hild:

NIH has an ACTIV webpage. They would like to update it to include you on the Therapeutics – Pre-clinical Working Group listing. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please let me know if we have your permission to list you on the NIH website.**

Please confirm if this listing is correct:

Sheri Hild, Ph.D.

Program Director for National Primate Research Centers

Office of Research and Infrastructure Program, NIH

Thank you.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19:

fnih.org/pandemic

<image001.png>

From: Melencio, Cheryl (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=279E14FA7428415BB86087D08B628E6F-MELENCIOC]
Sent: 9/30/2020 6:32:47 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: updated ACTIV roster

Thank you.

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

b6

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Brodd, Lauren (NIH/OD) [E] b6
Sent: Wednesday, September 30, 2020 2:29 PM
To: Melencio, Cheryl (FNIH) [T]
Cc: Parker, Ashley (NIH/OD) [E] b6
Subject: updated ACTIV roster

Hi Cheryl,

We updated our ACTIV excel roster file and wanted to send so you have for your records.

As an FYI, on this version (updated from 8/4 version), the following changes were made:

- Leadership organizations
 - Added Operation Warp Speed (govt) and Rhythm Therapeutics (industry)
 - Removed KSQ (industry)
- Participants
 - Added Isis Kanevsky and Sheri Hild
 - Removed Frank Stegmeier

Thanks,

Lauren

Lauren Brodd, Ph.D.
Health Science Policy Analyst
Division of Biosafety, Biosecurity, and Emerging Biotechnology Policy
Office of Science Policy
National Institutes of Health

b6



OSP Blog: [Under the Poliscopes](#)

Twitter: @CWolinetzNIH

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/9/2020 3:54:53 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Question about recently viewed senate testimony

Hi Ashley and Francis,

Just a quick note. This current review of Ivermectin is actually the third time the Agent Prioritization team has reviewed the agent. We are doing so now because of some of the emerging data. Francis, we will share that you received this note when we are adjudicating the agent.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, December 9, 2020 10:48 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Question about recently viewed senate testimony

Hi Francis,

As of 12/2 ivermectin is still under review for consideration in ACTIV-2, please see attached.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, December 9, 2020 10:39 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6]
Subject: FW: Question about recently viewed senate testimony

Hi Ashley,

See attached and below. Didn't the ACTIV prioritization group look at ivermectin? Is there anything here that should cause a reconsideration?

FC

APAR0000022358

From: Hardie, Thomas [b6]
Sent: Wednesday, December 9, 2020 9:39 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Question about recently viewed senate testimony

Dear Dr, Collins

I met you briefly when I was part of the NINR program in the summer of 2000. I am a retired full professor of Nursing from the University of Delaware and an adjunct full professor at the Univ. of Penn. Yesterday I watched the testimony of Pierre Kory, MD before the US Senate pleading for the NIH to review his submitted preprint of a meta analysis of the use of ivermectin for the treatment of COVID-19. I have attached his testimony for your review. I was shocked by his statement that to his knowledge there were no NIH panels reviewing existing treatments for COVID-19. If this is true, it is disheartening. I have read the preprint and believe it identifies a significant signal for the effectiveness of ivermectin. I have been an author, coauthor and reviewer on numerous database publications which is the basis of my conclusion. I am surprised that NIH would wait for the peer reviewers of Science before considering the meta analysis information to revise their treatment recommendation for early COVID-19. I am sure the NIH faculty can independently review the preprint and provide comment and guidance. If my conclusion or Dr. Cory's analysis are incorrect I would encourage the NIH to explain this to the treatment community. If the meta analysis is correct please pressure those responsible at the NIH to act with greater urgency as many of us may die waiting. The guiding principle of do no harm appears to be outweighed by the evidence in the meta analysis if it is correct. The current NIH recommendation from 8/202 appears to be go home and don't call me until you have trouble breathing. I am concerned that this recommendation may be a contributing factor in countries like India having lower case fatality rates than the US. Thank you for hearing my concerns.

Respectfully

Dr. Thomas L. Hardie NP RN
Sent from [Mail](#) for Windows 10

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 12/2/2020 1:34:55 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: TX portal

This is exactly what I was hoping for Ashley. Thanks!

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, December 2, 2020 at 8:31:47 AM
To: "Freire, Maria (FNIH) [T]" [b6] "Wholley, David (FNIH) [T]" [b6]
Subject: RE: TX portal

Hi Maria,

We updated the links on the NIH ACTIV website ~3 months ago to ensure all therapeutics are submitted directly to the ACTIV clinical/preclinical candidate portal (blue button on image below) reviewed by Deloitte/FNIH/et al. Only the vaccine candidates and other compounds can be submitted to the NIH COVID-19 portal (brown button on image below).

We are now receiving ~1-4 candidates every 1-2 weeks that came through the NIH COVID portal that we find relevant to ACTIV and we share the ACTIV link with the submitter to ensure those candidates can be reviewed by the ACTIV prioritization team.

<https://www.nih.gov/research-training/medical-research-initiatives/activ>



Please let us know if you need anything further.

Thanks,
Ashley

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, December 2, 2020 7:58 AM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: TX portal

I was looking at the slides this morning and I wondered if we are still getting new TX candidates put in. And if so, how many. My guess is it should have tapered off. M.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/13/2020 1:06:07 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Sorosa, Alex David [asorosa@deloitte.com]
Subject: RE: Letters for ACTIV-3 High Accruing Sites

Thanks, Ashley!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, October 12, 2020 8:52 PM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Sorosa, Alex David <asorosa@deloitte.com>
Subject: Re: Letters for ACTIV-3 High Accruing Sites

Hi Stacey,

I've forwarded the letters to FC for signature cc'ing you and Gretchen who can apply the signature once FC gives the green light.

Thanks,
Ashley

On Oct 12, 2020, at 5:29 PM, Adam, Stacey (FNIH) [T] [b6] wrote:

Hi Ashley,

I was hoping to ask your assistance in having Francis review a letter that we would like to have he and Janet's signatures on. OWS and Janet have already reviewed and approved, so all we need is FC's sign off/edits.

These letters are for the highest accruing sites for the ACTIV-3 trial as a thanks and congratulations, and well as an offer to help them continue their success. We would likely send a version of these out each month for the sites, so these should be considered as templates that we will tweak for each site.

If you feel like this should go through David, then I will have him send to FC.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Direct: b6 Mobile: b6

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11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

<image001.jpg> <image002.jpg> <image003.jpg> <image004.jpg>

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

<image005.png>

<ACTIV-3 High Accruers Letter 10092020-Intermountain.docx>

<ACTIV-3 High Accruers Letter 10092020-Vanderbilt.docx>

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/13/2020 1:05:40 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Letters for ACTIV-3 High Accruing Sites

Thanks, Ashley!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, October 12, 2020 8:50 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6] Wood, Gretchen (NIH/OD) [E] [b6]
Subject: re: Letters for ACTIV-3 High Accruing Sites

Hi Francis,

Please see attached ACTIV-3 letters below that need your signature.

Thanks,
Ashley

Begin forwarded message:

From: "Adam, Stacey (FNIH) [T]" [b6]
Date: October 12, 2020 at 5:28:53 PM EDT
To: "Parker, Ashley (NIH/OD) [E]" [b6]
Cc: "Sorosa, Alex David" <asorosa@deloitte.com>
Subject: Letters for ACTIV-3 High Accruing Sites

Hi Ashley,

I was hoping to ask your assistance in having Francis review a letter that we would like to have he and Janet's signatures on. OWS and Janet have already reviewed and approved, so all we need is FC's sign off/edits.

These letters are for the highest accruing sites for the ACTIV-3 trial as a thanks and congratulations, and well as an offer to help them continue their success. We would likely send a version of these out each month for the sites, so these should be considered as templates that we will tweak for each site.

If you feel like this should go through David, then I will have him send to FC.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: [b6] Mobile: [b6]

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/16/2020 11:24:02 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6] [b6] Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [asorosa@deloitte.com]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]
Subject: Summary of the ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: 2020-10-14_Trial_Oversight_Committee_Meeting_Summary.pdf

Dear ACTIV-2/3 TOC Members,

Please find attached the summary of the meeting on Wednesday. If you have any additions or amendments, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/30/2020 4:09:41 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Erica Ollmann Saphire [b6] Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Carver, Trea (NIH) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac05f976df484ed69022b8663cd448d3-carverkr]; Reich, Colleen [b6]; Lisbeth Jørgensen [b6]; Rose Li Central Account [FNIH@roseliassociates.com]; Dana Carluccio [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Jabarkhail, Mina [b6]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [hanasr@deloitte.com]
Subject: Summary of the ACTIV-2/-3 Trial Oversight Committee Meeting
Attachments: 2020-11-25_Trial_Oversight_Committee_Meeting_Notes.pdf

Dear ACTIV-2/3 Trial Oversight Committee and Guests,

Please find attached the notes from our call last Wednesday. If you have any additions or amendments, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health

Direct: [b6] Mobile: [b6]

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From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 9/22/2020 1:29:39 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]
Subject: RE: Confirmation of ACTIV-4c and ACTIV-5 launch

Thanks, Ashley!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, September 22, 2020 9:28 AM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Chen, Helen Q. <qingchen@deloitte.com>
Subject: RE: Confirmation of ACTIV-4c and ACTIV-5 launch

Thanks very much, Stacey! I've adjusted the timetable for the Secretary's meeting and let FC know.

Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Tuesday, September 22, 2020 9:15 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Chen, Helen Q. <qingchen@deloitte.com>
Subject: FW: Confirmation of ACTIV-4c and ACTIV-5 launch

Hi Ashley,

Please see the update on ACTIV-4c for FC.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Kindzelski, Andrei (NIH/NHLBI) [E] [b6]
Sent: Tuesday, September 22, 2020 9:12 AM
To: Adam, Stacey (FNIH) [T] [b6] Beigel, John (NIH) [E] [b6] Kindzelski, Andrei (NIH/NHLBI) [E] [b6] Hoots, W. Keith (NIH/NHLBI) [E] [b6]
Subject: Re: Confirmation of ACTIV-4c and ACTIV-5 launch

Hi Stacey,

The start of Convalescent trial was planned for the end of September/ early October.
As of now, eta is first week of October.

Thanks,
Andrei

From: "Adam, Stacey (FNIH) [T]" [b6]

Date: Monday, September 21, 2020 at 8:29:36 PM

To: "Beigel, John (NIH) [E]" [b6] "Kindzelski, Andrei (NIH/NHLBI) [E]" [b6]

Subject: FW: Confirmation of ACTIV-4c and ACTIV-5 launch

Hi John and Andrei,

Can you let me know if ACTIV-5 and ACTIV-4c will indeed launch this week? Or if not can you give me an ETA on the timing to give to FC?

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Monday, September 21, 2020 8:28 PM

To: Adam, Stacey (FNIH) [T] [b6]

Subject: Confirmation of ACTIV-4c and ACTIV-5 launch

Hi Stacey,

Dr. Collins has his meeting with the Secretary on Wednesday and we have the bullet below on the agenda. FC asked me to confirm if the launch of ACTIV-4c and ACTIV-5 are on schedule to launch this week before we send materials to HHS.

1. Projected launch of ACTIV-4 post-hospitalized and ACTIV-5 phase 2 inpatient trial, week of Sept. 21

Thanks,
Ashley

Ashley Parker, Ph.D.

Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

Office of the Director | National Institutes of Health

Tel: [b6]



National Institutes of Health

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 12/4/2020 2:36:12 PM
To: Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Eakin, Ann (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dafba298c194f9d9bc13c54fe0cf29a-eakinae]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Woodcock, Janet (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Read, Sarah (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=527b160038004a199ae6e0bac2226099-readsa]; Erbeling, Emily (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e976ebf7b14142fbb3c5c294efb334fe-erbelingej]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b4a14118481b4b39ba7e62a8d6425f79-Peter.Stein]; Judy Currier [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=890082c7c1e34902b0f535320cd16650-jscurrier.m]; Davey Smith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4eb666cbbac44a1a53dde4e9816f51d-DaveySmith]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; [b6]; [b6]; Kiley, James (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eae6b96b43b4dbcbff39382168a5c86-kileyj]; Goff, David (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=036113c7be0f42f897d1294cfbb99c10-goffdc]
CC: Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Reich, Colleen [b6]; Church, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d1761d52a54e4efa8c5f3f43dea3afaf-stanselleh]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Sorosa, Alex David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; Nasr, Hana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userfe0939a1]
Subject: RE: Summary of the ACTIV-2/-3 Trial Oversight Committee Meeting

Thanks, Lynn,

The ACTIV-3 team can certainly share these concerns with the team designing the sub-study and I am sure there will be lots of discussion on this as the effort progresses.

Thank you for taking time to review and provide your thoughts. Once we have a bit more resolution and discussion about where this will be run and the points below, we will circle back with the TOC.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]
Sent: Friday, December 4, 2020 9:33 AM
To: Adam, Stacey (FNIH) [T] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; Eakin, Ann (NIH/NIAID) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Woodcock, Janet (FDA/CDER) [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]; Erica Ollmann Saphire [b6]; Stein, Peter (FDA/CDER) [b6]; Judy Currier [b6]; Davey Smith [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Kiley, James (NIH/NHLBI) [E] [b6]; Goff, David (NIH/NHLBI) [E] [b6]
Cc: Chen, Helen Q. <qingchen@deloitte.com>; Bugin, Kevin (FDA/CDER) [b6]; Reich, Colleen [b6]; Church, Elizabeth (NIH/NIAID) [E] [b6]; Teyhen, Deydre (HHS/IOS) [b6]; Sorosa, Alex David <asorosa@deloitte.com>; Erhardt, William (HHS/IOS) [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Nasr, Hana <hanasr@deloitte.com>
Subject: RE: Summary of the ACTIV-2/-3 Trial Oversight Committee Meeting

Thank you Stacey.

I appreciate being able to see the draft study synopsis.

As written, it certainly seems reasonable and I'm confident the team will outline when the primary study analysis will be provided [b5]

[b5] I'll leave the obvious implications for budget and resource to [b5]
[b5] or to others to decide.

b5

I appreciate the team taking time to provide the synopsis. I don't wish to make this more complicated than necessary but I am uncomfortable just allowing investigators to select standard of care in the factorial design setting in that we may have lost equipoise for some of those quadrants. Thus would be helpful to see the factorial design elements outlined in the context of SOC background.

Best regards

APAR0000022408

Lynn

Gilbert 'Lynn' Marks, MD
Senior Advisor to BARDA OD and OWS Therapeutics
Tunnell Government Services
Contractor supporting the mission of:
Biomedical Advanced Research and Development Authority (BARDA)
Assistant Secretary for Preparedness and Response (ASPR)
Department of Health and Human Services (HHS)
200 C St SW
O'Neill Bldg
Washington, DC 20024
b6

From: Adam, Stacey (FNIH) [T] b6
Sent: Thursday, December 3, 2020 9:01 PM
To: Higgs, Elizabeth (NIH/NIAID) [E] b6; Eakin, Ann (NIH/NIAID) [E] b6; Lane, Cliff (NIH/NIAID) [E] b6; Wholley, David (FNIH) [T] b6; Woodcock, Janet (FDA/CDER) b6; Marks, Gilbert (OS/ASPR/BARDA) (CTR) b6; Bozzette, Sam (NIH/NCATS) [E] b6; Read, Sarah (NIH/NIAID) [E] b6; Erbelding, Emily (NIH/NIAID) [E] b6; Erica Ollmann Saphire b6; Stein, Peter (FDA/CDER) b6; Judy Currier b6; Davey Smith b6; Kim, Peter (NIH/NIAID) [E] b6; Kiley, James (NIH/NHLBI) [E] b6; Goff, David (NIH/NHLBI) [E] b6
Cc: Chen, Helen Q. <qingchen@deloitte.com>; Bugin, Kevin (FDA/CDER) b6; Reich, Colleen b6; Church, Elizabeth (NIH/NIAID) [E] b6; Teyhen, Deydre (HHS/IOS) b6; Sorosa, Alex David <asorosa@deloitte.com>; Erhardt, William (HHS/IOS) b6; Melencio, Cheryl (FNIH) [T] b6; Parker, Ashley (NIH/NCI) [F] b6; Harrigan, Rachel (HHS/IOS) b6; Nasr, Hana <hanasr@deloitte.com>
Subject: Summary of the ACTIV-2/-3 Trial Oversight Committee Meeting

Dear ACTIV-2/3 TOC,

Thank you all for a very productive discussion yesterday. Please find attached the summary of yesterday's meeting for your review. If you have any additions or amendments, please let me know.

In addition, please find attached the proposed concept from Sam Brown and the ACTIV-3 team for the Aviptadil agent. Please feel free to provide any feedback that you may have. Please keep in mind that this is still very much in draft as the team is still working on it. Please do not distribute beyond this group.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: b6 | Mobile: b6
fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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APAR0000022408



From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/19/2020 3:42:02 PM
To: Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]; Kim, Peter (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c48148e476824ce893260acf33b0f774-kimp2]; McNay, Laura (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d089e838a3824b60b91b6c394fedd335-lmcnay]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bfdccfda71ced-jatkinso]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Beigel, John (NIH) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=492ae062f7d74e3cbd894e30160869f0-jbeigel]; Dunsmore, Sarah (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eada7-Gilbert.Mar]; Thomas Stock [b6]; Erhardt, William (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86d3f82263b04011a1ff30220cd2d612-William.Erh]; Harrigan, Rachel (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f4c4e7fa8c48359fe7fdcef26cbabc-Rachel.Harr]; David Douglas [b6]; Douglas, David (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=febabc96e8d04b5fa51d5749ad0c74a6-David.Dougl]; Stock, Thomas (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cb470e0376340ee8a234fd4331fed3d-Thomas.Stoc]
CC: Parker, CAPT Sheri (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a97ee0e31744d92906e5722b8c25302-Sheri.Parke]; Philip, Ritika [b6]; Lawlor, Ciarán [b6]; Chen, Helen Q. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user34aa917e]; Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturieria]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Teyhen, Deydre (HHS/IOS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c75b09732dc14cfcb346afd7671ee69f-Deydre.Teyh]; Higgs, Elizabeth (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0601ca55a82841aba16353b96cff8ca9-ehiggs]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; VND Shreeve, Chris [b6]; Knox, Shamay (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=870b562ab9084927872c9e162d520cde-sknox]; Decastro, Philip (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b5170c536b3488bb061cece532cc46e-decastropj]; Illanes, Christine (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=637015ad1b36455fa152a8969b4d4e30-illanescri]; Ramakrishnan, Raahul [b6]; Kuethe, Christine (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6979825f6c648b5be16a3050b4a0a03-Christine.K]; asorosa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userffc6da86]
Subject: Summary from ACTIV Cross Trial Operations Strategy/Problem Solving Meeting
Attachments: ACTIV_Cross-Trial Ops Meeting_20201015.pdf

Dear ACTIV Trial Ops Leads,

Please find attached the summary and action items from our meeting on Thursday. Please let me know if you have any questions, additions, or amendments.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: [b6] | Mobile: [b6]

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/30/2020 4:39:05 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: NIH staff on ACTIV working groups

Ok, happy to raise if you get loaded with other items – thank you.

Ashjley

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 12:37 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

No, we raised it on a previous war room call but never got beyond the musing stage.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 12:21 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

Hi David,

We need to raise the identification of industry co-chair for the ACTIV executive committee on the call this afternoon unless this has been taken care of.

Thank you,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, April 30, 2020 12:17 PM
To: Myles, Renate (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

Hi Renate,

This has not been discussed further, as you know the WH briefing and other urgent items overshadowed. I will raise this issue on our war room call this afternoon – Francis will be the exec. comm. co-chair for NIH, however the industry co-chair still needs to be identified.

I will circle back after the call at 5:30pm today.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Thursday, April 30, 2020 11:57 AM

To: Parker, Ashley (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]

Subject: RE: NIH staff on ACTIV working groups

Hi Ashley:

Any update on the executive committee and co-chairs?

Renate

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Monday, April 27, 2020 2:55 PM

To: Wolinetz, Carrie (NIH/OD) [E] [b6] Myles, Renate (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]

Subject: RE: NIH staff on ACTIV working groups

The staff list is correct with the addition of Walter K to the clinical tx group – please see attached.

The executive committee for the overall initiative has not yet been established – the co-chairs will more than likely be Francis and someone from industry but not Cliff Lane. Can they hold off on listing co-chairs for the overall initiative until this is decided?

Thanks,
Ashley

From: Wolinetz, Carrie (NIH/OD) [E] [b6]

Sent: Monday, April 27, 2020 10:50 AM

To: Myles, Renate (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]

Subject: RE: NIH staff on ACTIV working groups

I don't think we need approvals to have staff listed, but Ashley could probably verify that the list is correct. And I think listing Cliff as co-chair is correct.

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Monday, April 27, 2020 10:48 AM

To: Wolinetz, Carrie (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]

Subject: FW: NIH staff on ACTIV working groups

Importance: High

Hi Carrie and Ashley:

Who needs to okay the listing of our folks names on the FNIH website? We're so use to these kind of things that I really don't think we need approvals, but just double checking. Also, I'm assuming Cliff Lane will be listed as a co-chair of the overall effort?

Renate

From: Gorman, Greta (FNIH) [T] [b6]
Sent: Monday, April 27, 2020 10:44 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Meltzer, Abbey (FNIH) [T] [b6]
Subject: NIH staff on ACTIV working groups

Dear Renate,

We are working to finalize permission from all ACTIV working group members to list their names publicly on our FNIH website.

Attached is the list of working group members who are NIH staff. We heard from some of the NIH staff that this had to go through NIH channels (possibly through Dr. Collins) to grant permission for the NIH employees to be listed.

Will you please pass this through the proper channels to secure NIH's permission to list these names?

Thank you!

Best,
Greta

Greta Gorman
Director of Communications
Foundation for the National Institutes of Health
[b6] | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/29/2020 12:23:41 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Update ACTIV Partner Slide

Thank you, David and Nina – greatly appreciate it.

Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, April 28, 2020 8:13 PM
To: Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Update ACTIV Partner Slide

Formatting on the logos for BARDA and EMA looked a little off, so I fixed 'em.

From: Gonzalez, Nina <ningonzalez@deloitte.com>
Sent: Tuesday, April 28, 2020 7:57 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Update ACTIV Partner Slide

Hi David –

See attached revised partner slide with addition of Nancy Messonnier from CDC.

Let me know if you need anything else.

Nina Gonzalez

Nina Gonzalez
Deloitte Consulting LLP
Tel/Direct: +1 202 748 6535
ningonzalez@deloitte.com | www.deloitte.com

Please consider the environment before printing.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, April 28, 2020 7:38 PM
To: Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: [EXT] FW: Update ACTIV Partner Slide

Yes, forwarding to our engagement lead, Nina Gonzalez, to get this done.

APAR0000014227

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 7:03 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Update ACTIV Partner Slide

Hi David,

Can the Deloitte team please update the partner slide to include CDC? Francis has already sent the slides forward for the WH briefing tomorrow but the logo and contact will need to be added for the presentation to Congress Thursday, 4/30. Can we have a updated version by tomorrow morning?

I'm attaching the most recent version.

Thank you,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, April 28, 2020 6:47 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: TIME SENSITIVE - WH Slides updated

I'm looking back at the ACTIV press release 4/17 and noticed we had CDC listed as a partner. Is there a reason for omitting them on the partner slide? Nancy Messonnier is the person we have representing CDC on the master list.

Thanks,
Ashley

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/29/2020 12:22:22 AM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: FW: Update ACTIV Partner Slide
Attachments: WH_ACTIV_042920 Updated 754pm NGdw.pptx

FYI

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, April 28, 2020 8:13 PM
To: Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Collins, Francis (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Update ACTIV Partner Slide

Formatting on the logos for BARDA and EMA looked a little off, so I fixed 'em.

From: Gonzalez, Nina <ningonzalez@deloitte.com>
Sent: Tuesday, April 28, 2020 7:57 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Update ACTIV Partner Slide

Hi David –

See attached revised partner slide with addition of Nancy Messonnier from CDC.

Let me know if you need anything else.

Nina Gonzalez

Nina Gonzalez
Deloitte Consulting LLP
Tel/Direct: +1 202 748 6535
ningonzalez@deloitte.com | www.deloitte.com

Please consider the environment before printing.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, April 28, 2020 7:38 PM
To: Gonzalez, Nina <ningonzalez@deloitte.com>
Cc: Collins, Francis (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: [EXT] FW: Update ACTIV Partner Slide

Yes, forwarding to our engagement lead, Nina Gonzalez, to get this done.

From: Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>
Sent: Tuesday, April 28, 2020 7:03 PM

APAR0000014229

To: Wholley, David (FNIH) [T] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Update ACTIV Partner Slide

Hi David,

Can the Deloitte team please update the partner slide to include CDC? Francis has already sent the slides forward for the WH briefing tomorrow but the logo and contact will need to be added for the presentation to Congress Thursday, 4/30. Can we have a updated version by tomorrow morning?

I'm attaching the most recent version.

Thank you,
Ashley

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Sent: Tuesday, April 28, 2020 6:47 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: TIME SENSITIVE - WH Slides updated

I'm looking back at the ACTIV press release 4/17 and noticed we had CDC listed as a partner. Is there a reason for omitting them on the partner slide? Nancy Messonnier is the person we have representing CDC on the master list.

Thanks,
Ashley

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/28/2020 8:54:37 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: FW: DoD Representatives
Attachments: WH_ACTIV_042920 Updated (004)_Plus DOD and Gen. Talley.pptx

Oh My -- I've added Brig. Gen. Talley his government agency logo and a logo for DOD -- can't fit.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 4:31 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: DoD Representatives

Can we quickly add Brigadier General Talley and DoD to the ACTIV roster slide? I'd like to be able to show we're connected -- BG Talley will be in the room tomorrow at the WH.

FC

-----Original Message-----

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Tuesday, April 28, 2020 4:26 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Subject: DoD Representatives

BG Talley concurs with the following nominees to support the ACTIV initiative:

Executive Group: BG Talley (Dr. Dertzbaugh backup),

[b6]

Preclinical: Dr. Louise Pitt, USAMRIID, [b6]

Clinical: CAPT Tim Burgess, USUHS, [b6]

Vaccines: Dr. Nelson Michael, WRAIR, [b6]

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/28/2020 8:33:05 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: DoD Representatives

Of course we can -- will do now.

Ashley

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 4:31 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
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To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/27/2020 6:22:38 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: COVID-19 public-private partnership

Thanks!

From: Freire, Maria (FNIH) [T] [b6]
Sent: Monday, April 27, 2020 2:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: COVID-19 public-private partnership

Ashley, FYI.

From: Fischbeck, Kenneth (NIH/NINDS) [E] [b6]
Sent: Thursday, April 23, 2020 10:35 PM
To: Freire, Maria (FNIH) [T] [b6]
Cc: Nath, Avindra (NIH/NINDS) [E] [b6]; Vivian Cheung [b6]; Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: COVID-19 public-private partnership

Thanks for the word, Maria.

I appreciate your attending to it!

Kurt

Sent from my iPhone

On Apr 23, 2020, at 9:35 PM, Freire, Maria (FNIH) [T] [b6] wrote:

I responded to your April 17th e-mail within 6 minutes of receiving it, letting you know that I was sending it to my folks, which I did immediately.

Tachi Yamada, at Vivian Cheung's request also contacted me a day later, Saturday, April 18th, regarding this compound. In my response to Tachi that same afternoon, I clarified the process. Perhaps Vivian did not have a chance to send it to you. It is below.

In addition, immediately upon receipt of the copy of your e-mail to me, Dr. Collins sent your note to the NIAID staff who is also collecting this information in their database. He and I confirmed we had both put it on the list for consideration.

This afternoon, again, I confirmed that this is on the list to be reviewed with the rest of other compounds for prioritization. You will be contacted by a member of the Working Group should your compound be selected.

Maria

APAR0000014327

From: Freire, Maria (FNIH) [T]
Sent: Saturday, April 18, 2020 6:21 PM
To: Tachi yamada <[b6]>
Subject: RE: COVID-19 public-private partnership

Hello Tachi! It is always to good to hear from you.

Yes, I have thought over and over again how different things would be if they had paid attention to the recommendations. If nothing else we would have a speedier vaccine process! Do you think the world will finally pay attention after this is done? I have become a skeptic.

As life would have it, [b6] when the government shut down the borders and put the country on lockdown, which is still the case. Unlike travelers and tourists, [b6] [b6], so we are well, healthy and safe. Safer probably than in the USA, I am very sorry to say. The issue is the return. They have cancelled our flights 3 times already. My ticket is for May 15th now... we will see. If this keeps up, I will seek repatriation through the American Embassy. Nevertheless, being here is the same as teleworking [b6] – just a bit father away.

Indeed, ACTIV just launched and we have been front and center, working hand in hand with Francis and the companies. It has been non-stop. I have done this before, as you know, but this is on steroids and at warp speed.

I saw the note from Kurt, which included Vivian and Francis. Let me assure you that my reply was not a polite brush-off – it is part of the process. We have gotten inundated by similar requests, many of which are frivolous or fishing expeditions. Others, like the one below, are taken very seriously.

As background, ACTIV has 4 workstreams, each with a dedicated working group (WG):

1. Standardize and share preclinical evaluation methods in an open forum that allows for comparison and validation
2. Prioritize and accelerate clinical evaluation of therapeutic candidates with near-term potential
3. Maximize clinical trial capacity and effectiveness
4. Advance vaccine development

The WG for workstream 2 is charged with establishing a plan for prioritizing candidates for clinical evaluation. Considerations include a process for making this nimble and fast, prioritizing candidates with different methods of action, rather than multiple candidates with the same methods of action, and leveraging prioritization efforts already done by others, like what is currently being done in the UK (with which we are coordinating). There is no benefit in duplication or redundancy – and there is no time to waste.

What I did immediately upon receiving Kurt's note, as I have done with other similar ones, is to forward it to the person leading this workstream, who is part of the FNIH. They know this is a serious request and it has been placed in the group.

As you know very well, I cannot nor will I try to influence the decision of the WG experts but I am certain that they will review this information and seek additional clarification as needed.

I hope this is helpful and will give Vivian assurances that the note has been placed where it will be appropriately considered.

All the best and stay safe! Maria

From: Tachi yamada { b6 }
Sent: Saturday, April 18, 2020 4:57 PM
To: Freire, Maria (FNIH) [T] { b6 }
Subject: Fwd: COVID-19 public-private partnership

Hi Maria - I hope you are well and keeping safe! - I know lots of people were stuck { b6 } at the beginning of the pandemic and my hope was that you were not among them - doesn't it seem ironic to you to see all that is going on right now and how some of the many issues might have been avoided if people had paid closer attention to the recommendations of the work that we did on the Commission in 2014? - I read that Francis has set up public-private initiative to support COVID-19 vaccines (and treatments?) - along these lines Vivian sent me this note and I thought I would reach out to you to learn about how you are managing through this tumultuous time - would it be possible to touch base by phone sometime soon? - many thanks - Tachi

Begin forwarded message:

From: "Cheung, Vivian" { b6 }
Date: April 18, 2020 at 7:01:53 AM PDT
To: Tachi yamada { b6 }
Subject: Fw: COVID-19 public-private partnership

Hi Tachi,

Following the private-public partnership to develop vaccines against COVID-19, some at the NIH are thinking of developing a similar group to develop treatments. I continue to be involved with NIH and Ionis towards this effort but of course, a broader collaboration will be much more effective. I told our NIH and Ionis colleagues that I would reach out to you to see if you can help with some leadership and coordination. Your experience with international vaccine development and your relationship with FNIH are critically needed. As you can imagine that while this group has lots of passion, real-world experience is not the strength.

Please see emails below - and I can fill in more by phone/ email. I also talked to Mukesh and he said that he would be willing to help administratively in any way he can.

Many thanks
Viv

From: Freire, Maria (FNIH) [T] { b6 }
Sent: Friday, April 17, 2020 6:44 PM
To: Fischbeck, Kenneth (NIH/NINDS) [E]; Collins, Francis (NIH/OD) [E]
Cc: Nath, Avindra (NIH/NINDS) [E]; Cheung, Vivian; Eric Swayze
Subject: RE: COVID-19 public-private partnership

APAR0000014327

External Email - Use Caution

Thank you, Kurt. I appreciate your note. Let me send it to my folks for follow-up. All the best, Maria

From: Fischbeck, Kenneth (NIH/NINDS) [E] <[REDACTED] b6 [REDACTED]>
Sent: Friday, April 17, 2020 6:38 PM
To: Freire, Maria (FNIH) [T] <[REDACTED] b6 [REDACTED]>; Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: Nath, Avindra (NIH/NINDS) [E] <[REDACTED] b6 [REDACTED]>; Vivian Cheung <[REDACTED] b6 [REDACTED]>; Eric Swayze <[REDACTED] b6 [REDACTED]>
Subject: COVID-19 public-private partnership

It was good to see the announcement today about the public-private partnership for COVID-19 vaccine and therapeutics development.

We have been working with Ionis Pharmaceuticals and NIAID on developing and testing an oligonucleotide therapeutic for COVID-19. Ionis has been very successful in developing oligonucleotide therapy for other diseases, and it has relevant experience with SARS1 and cystic fibrosis.

This collaborative project could be a good fit for the public-private partnership. Please let us know how best to connect with it.

Thanks!

Kurt Fischbeck

Electronic Mail is not secure, may not be read every day, and should not be used for urgent or sensitive issues

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/27/2020 10:51:09 PM
To: Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]
Subject: RE: NIH staff on ACTIV working groups

There is a need to set up a exec. comm for ACTIV and there will likely be two co-chairs: one will be Francis and the other will be someone from industry.

From: Gladman, Jordan (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 6:34 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

What was decided?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 6:32 PM
To: Gladman, Jordan (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

FC reached out and we got the answer – thanks!

From: Gladman, Jordan (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 6:00 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

Did he get back to you?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 12:00 PM
To: Gladman, Jordan (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

OH MY!

From: Gladman, Jordan (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 11:59 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

He said he got 1000 email this weekend.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 11:59 AM
To: Gladman, Jordan (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

Ok, let's wait it out. I need to get better at cc'ing you on emails.

Thanks!

From: Gladman, Jordan (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 11:57 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

Do you want me to follow-up with him. He will probably check his emails as soon as he finished this meeting.

He might suggest Francis and Tony.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 11:53 AM
To: Gladman, Jordan (NIH/OD) [E] [b6]
Subject: FW: NIH staff on ACTIV working groups

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, April 27, 2020 11:31 AM
To: Lane, Cliff (NIH/NIAID) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: RE: NIH staff on ACTIV working groups

Thank you, Cliff. Larry – should we list you and Francis as the co-chairs for the overall effort? Other ICDs I've listed below?

Thanks,
Ashley

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Monday, April 27, 2020 11:28 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: Re: NIH staff on ACTIV working groups

Thanks for asking. I would see myself more in the role of support staff than co-chair. The others are at the level of NIH or IC Directors/NIH Deputy Director and more appropriate in the co-chair role.

Cliff

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Monday, April 27, 2020 at 11:24 AM
To: "Lane, Cliff (NIH/NIAID) [E]" [b6]; Lawrence Tabak [b6]
Subject: RE: NIH staff on ACTIV working groups

Hi Cliff,

I want to ensure that you are OK with being listed on FNIH's website as a co-chair for the overall effort for ACTIV. If FNIH plans to list NIH co-chairs for the overall effort, it seems this should be Francis, Larry, Tony, Cliff, and Chris Austin?

Cc'ing Larry for input as well.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 10:48 AM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]
Subject: FW: NIH staff on ACTIV working groups
Importance: High

Hi Carrie and Ashley:

Who needs to okay the listing of our folks names on the FNIH website? We're so use to these kind of things that I really don't think we need approvals, but just double checking. Also, I'm assuming Cliff Lane will be listed as a co-chair of the overall effort?

Renate

From: Gorman, Greta (FNIH) [T] [b6]
Sent: Monday, April 27, 2020 10:44 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Meltzer, Abbey (FNIH) [T] [b6]
Subject: NIH staff on ACTIV working groups

Dear Renate,

We are working to finalize permission from all ACTIV working group members to list their names publicly on our FNIH website.

Attached is the list of working group members who are NIH staff. We heard from some of the NIH staff that this had to go through NIH channels (possibly through Dr. Collins) to grant permission for the NIH employees to be listed.

Will you please pass this through the proper channels to secure NIH's permission to list these names?

Thank you!

Best,
Greta

Greta Gorman
Director of Communications
Foundation for the National Institutes of Health
[b6] | fnihi.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnihi.org/pandemic

APAR0000014362



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/27/2020 4:25:54 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]
Subject: RE: NIH staff on ACTIV working groups

In addition to listing the co-chairs for the working groups which does include one industry rep and one NIH rep – FNIH wants to list NIH “Co-chairs” for the overall initiative on their website.

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 12:22 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Subject: Re: NIH staff on ACTIV working groups

Wouldn't the co-chair be from Industry?

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Monday, April 27, 2020 at 11:24 AM
To: "Lane, Cliff (NIH/NIAID) [E]" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: RE: NIH staff on ACTIV working groups

Hi Cliff,

I want to ensure that you are OK with being listed on FNIH's website as a co-chair for the overall effort for ACTIV. If FNIH plans to list NIH co-chairs for the overall effort, it seems this should be Francis, Larry, Tony, Cliff, and Chris Austin?

Cc'ing Larry for input as well.

Thanks,
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 10:48 AM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]
Subject: FW: NIH staff on ACTIV working groups
Importance: High

Hi Carrie and Ashley:

Who needs to okay the listing of our folks names on the FNIH website? We're so use to these kind of things that I really don't think we need approvals, but just double checking. Also, I'm assuming Cliff Lane will be listed as a co-chair of the overall effort?

Renate

From: Gorman, Greta (FNIH) [T] [b6]
Sent: Monday, April 27, 2020 10:44 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Meltzer, Abbey (FNIH) [T] [b6]
Subject: NIH staff on ACTIV working groups

Dear Renate,





We are working to finalize permission from all ACTIV working group members to list their names publicly on our FNIH website.

Attached is the list of working group members who are NIH staff. We heard from some of the NIH staff that this had to go through NIH channels (possibly through Dr. Collins) to grant permission for the NIH employees to be listed.

Will you please pass this through the proper channels to secure NIH's permission to list these names?

Thank you!

Best,
Greta

Greta Gorman
Director of Communications
Foundation for the National Institutes of Health
[b6] | fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852
   

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/27/2020 1:13:41 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: FW: NIH/BARDA/FDA relationship for COVID-19 therapeutics
Attachments: Screen Shot 2020-04-26 at 9.53.50 PM copy.png

Hi Jill,

Please see diagram per our discussion, attached.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 8:27 AM
To: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: FW: NIH/BARDA/FDA relationship for COVID-19 therapeutics

For discussion at war room this morning...

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Sunday, April 26, 2020 10:00 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: NIH/BARDA/FDA relationship for COVID-19 therapeutics

Francis,
The diagram does not offer the possibility for any other input, prioritization than via ACTIV. What if you had an interesting idea emerge from the UK or from DOE following their massive data mining exercises. Do you envision everything going through ACTIV?

I think you need another element, between your prioritized therapeutic candidates and the trials – you need an ASPR/NIH go/no go check point to emphasize how decisions will ultimately be made.

(BTW, The diagram you sent was upside down; I attach a version right side up in case others had the same issue).

Larry

From: Francis Collins [b6]
Date: Sunday, April 26, 2020 at 9:47 PM
To: Janet Woodcock [b6]; "Johnson, Robert (OS/ASPR/BARDA)" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]; "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: NIH/BARDA/FDA relationship for COVID-19 therapeutics

Hi all,

Thanks for your time on the phone this evening. It was very helpful to talk through the ways we can ensure that NIH, FDA, and BARDA are working effectively together on COVID-19 therapeutics.

I came away with the following conclusions and action items:

- 1) The way in which ACTIV intersects with BARDA and FDA decision making needs clarity. I attach a hand-drawn diagram that helped me envision this, but please weigh in on whether you think this captures the flow of decision-making correctly. Once blessed by you all, it could be drawn up professionally and could be one of the slides for Wednesday.
- 2) NIAID/NIH needs to assess whether the right SMEs with the right level of seniority are serving on BARDA's interagency panels, in order to represent the agency priorities effectively.
- 3) The role of the therapeutics working group of the MCM Task Force (to be chaired by Janet) needs to be better defined. (In fact, this seems to an opportune moment to re-evaluate the charge to the whole MCM Task Force.)
- 4) Need to find out more about DOD's role (and who is presenting) in the Wednesday WH meeting.
- 5) Need to synthesize the WH presentation between therapeutics and vaccines, and finalize.
- 6) Kadlec and Collins need to take the role of overseeing the very promising new world order between NIH and ASPR/BARDA.

Did I miss anything?

Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/26/2020 8:11:40 PM
To: Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]
Subject: FW: repurposed oncology drug shows in-vitro activity with COVID-19
Attachments: 390431 - ICO to ES Confirmation

390431 - ICO to ES Confirmation – FYI.

From: Parker, Ashley (NIH/OD) [E]
Sent: Sunday, April 26, 2020 4:02 PM
To: Freire, Maria (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6] Meltzer, Abbey (FNIH) [T] [b6]
Cc: Pollock, Rachel (NIH/OD) [E] [b6]
Subject: RE: repurposed oncology drug shows in-vitro activity with COVID-19

Hi Maria,

Received – thank you.

Ashley

From: Freire, Maria (FNIH) [T] [b6]
Sent: Sunday, April 26, 2020 12:54 PM
To: Adam, Stacey (FNIH) [T] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Fwd: repurposed oncology drug shows in-vitro activity with COVID-19

Ashley,

I will start sending you these. Best, Maria

Begin forwarded message:

From: "Earle T. Holsapple" [b6]
Date: April 26, 2020 at 11:06:38 AM GMT-5
To: "Freire, Maria (FNIH) [T]" [b6]
Cc: Brian Leyland-Jones [b6]
Subject: repurposed oncology drug shows in-vitro activity with COVID-19

Dear Dr. Freire:

We are writing you to seek advice in determining how our clinic-ready, repurposed oncology drug, for use in treating COVID-19, can receive a quick evaluation and, hopefully, be added to the list of therapeutic candidates that meet ACTIV's requisites for consideration.

SciTech Development, LLC (SciTech) is a clinical stage, biopharmaceutical company that has reformulated a well-known and highly-studied, safe retinoid, fenretinide, by overcoming its bioavailability shortcoming. SciTech's lead product, ST-001 nanoFenretinide, is clinic ready (IND in hand for a non-Hodgkin's lymphoma trial).

Published data makes the case for fenretinide and, by inference, ST-001's use in treating COVID-19. Fenretinide and/or ST-001 have recently demonstrated antiviral activity against SARS-CoV-2 and MERS-CoV-2 and also previously against Dengue, Zika, West Nile, and HIV, viruses. This recorded antiviral activity and its likely immune effects, taken in conjunction with the API's known safety and tolerability profile, makes it an ideal candidate to repurpose for use with COVID-19. We are attaching two one-page documents that quickly summarize the opportunity and MoAs (We suggest these are read before proceeding).

SciTech filed a white paper with both BARDA and NIAID several weeks ago and have heard nothing since. We believe this therapeutic opportunity is too important and timely to be lost in a long review process and warrants immediate consideration.

The development of ST-001 as a drug to treat COVID-19 finds alignment with the medical countermeasure goals of BARDA and the strategic goals of PHEMCE through four key features of our proposition:

1. Early availability to the US healthcare system,
2. Fenretinide and/or ST-001's demonstrated efficacy profile versus Coronaviruses,
3. Readiness of large-scale production upon positive clinical evaluation of ST-001, and
4. Broad impact of proposed clinical investigations beyond COVID-19.

SciTech is presently in negotiations with two large, Midwest healthcare systems to conduct the clinical trial. Last Friday, the company filed a pre-IND application, that cross files with our active IND, for the use of ST-001 in treating COVID-19 patients. We are poised to act quickly and would greatly benefit from government support and/or corporate collaboration.

The rapidly expanding insights into clinical (in particular ICU) care for COVID-19 patients, their pathologic processes and parameters, and SARS-CoV-2 processes unveiled three key drivers of the disease that are direct targets of fenretinide. First, direct inhibition of viral replication would decrease viremia. Second, COVID-19 is strongly associated with increases of both IL-6 and IL-22 immune pathways, reportedly with detrimental implications in some patients (i.e. cytokine storm). SciTech hypothesizes that IL-6 and IL-22 can be controlled by Fenretinide directly inhibiting inflammation and resulting cytokine storm damage. Third, direct communications with critical care physicians and recent research indicate that free radicals might cause organ damage due to an inability to neutralize these. Fenretinide acts as an antioxidant.

Based on the above, we would appreciate guidance on the best approach for receiving serious consideration of our promising COVID-19 therapeutic.

Respectfully seeking your guidance,

Brian Leyland-Jones, MD, PhD
Chief Medical Officer

b6

Earle T. Holsapple
President

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/23/2020 1:05:14 AM
To: James, Stephanie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f0032ef62ca343dfb4bf79577e2aa8d1-jamesst]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: novel approach to COVID-19 vaccine

Received – thanks, Stephanie.

Ashley

From: James, Stephanie (FNIH) [T] [b6]
Sent: Wednesday, April 22, 2020 8:48 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: FW: novel approach to COVID-19 vaccine

Dear Ashley,

I am one of the FNIH folks involved in the ACTIV project. I understand you are collating all the unsolicited offers for help on the project, and am forwarding the one below for your files.

Best regards,
Stephanie

Stephanie James, PhD FASTMH
Senior Vice President, Science
Foundation for the National Institutes of Health
[b6]
www.fnih.org
11400 Rockville Pike Suite 600, North Bethesda, MD 20852

From: Caroline Kurtz [b6]
Sent: Wednesday, April 22, 2020 6:58 PM
To: James, Stephanie (FNIH) [T] [b6]
Cc: Michaela Dankova [b6]
Subject: novel approach to COVID-19 vaccine

Dear Stephanie,

I am reaching out to you as a contact on the FNIH site for information regarding grant opportunities for a COVID-19 vaccine. I lead programs at a small Biopharma company in Cambridge MA called Synlogic Inc (www.synlogictx.com), and we are interested in applying for funding to support development of a vaccine for COVID-19 using our platform. We especially need support to test safety and efficacy of the vaccine in preclinical models under BSL3 conditions. Our proposal is as follows:

Synlogic Inc. proposes to develop a vaccine for the prevention of COVID19 utilizing its synthetic biology platform to engineer probiotic bacteria to express viral antigens and immune activators/adjuvants. This vaccine will be based on an engineered E. coli Nissle (EcN) bacterial strain that will express viral proteins from

SARS-CoV2, the causative agent for COVID-19, and can be administered intranasally to induce protective immunity systemically and at mucosal surfaces. This vaccine can be manufactured in our GMP facilities to produce millions of doses from a single batch. As a lyophilized bacterial cell product, it is expected to have good room temperature stability.

We would be in preclinical development of this vaccine candidate, but already have an engineered E. coli Nissle strain currently in clinical trials for oncology, that can be rapidly adapted for this purpose. The grant would allow us to engineer the strain and test it in preclinical models to get a candidate for clinical studies.

Our questions are:

1. Is this project of interest to FNIH? (we could provide an abstract if you need to read more detail to know)
2. Is grant funding available for small businesses?
3. Would a phone call facilitate determining level of interest for this work?
4. What is the process to apply?

Thanks very much for your help and if I should direct my inquiry elsewhere, please advise.

Sincerely,

Caroline Kurtz

Caroline Kurtz, PhD
SVP, Head of Portfolio Strategy and Product Development
Synlogic Inc
301 Binney Street, Suite 402
Cambridge MA, 02142

This message (including any attachments) may contain confidential, proprietary, and/or private information. The information is intended to be for the use of the individual or entity designated above. If you are not the intended recipient of this message, please notify the sender immediately, and delete the message and any attachments. Any disclosure, reproduction, distribution or other use of this message or any attachments by an individual or entity other than the intended recipient is prohibited.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 4/23/2020 1:47:02 PM
To: Pollock, Rachel (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4887cb3513e242dfa7d2df712dcc6d6a-pollockrc]
CC: Coley, Gwendolyn (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b83abc06a7ff4579a184de4a34963079-coleygc]; Twyman, Leslie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e26841aed14cbcb1b8758e51283543-twymanle]
Subject: RE: novel approach to COVID-19 vaccine

Great – thank you.

Ashley

From: Pollock, Rachel (NIH/OD) [E] [b6]
Sent: Thursday, April 23, 2020 9:40 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Coley, Gwendolyn (NIH/OD) [C] [b6]; Twyman, Leslie (NIH/OD) [E] [b6]
Subject: RE: novel approach to COVID-19 vaccine

Yep – it worked!

Rachel Pollock

O: [b6]
C: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, April 22, 2020 11:51 PM
To: Pollock, Rachel (NIH/OD) [E] [b6]
Cc: Coley, Gwendolyn (NIH/OD) [C] [b6]; Twyman, Leslie (NIH/OD) [E] [b6]
Subject: FW: novel approach to COVID-19 vaccine

FYI.

From: James, Stephanie (FNIH) [T] [b6]
Sent: Wednesday, April 22, 2020 8:48 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: FW: novel approach to COVID-19 vaccine

Dear Ashley,

I am one of the FNIH folks involved in the ACTIV project. I understand you are collating all the unsolicited offers for help on the project, and am forwarding the one below for your files.

Best regards,
Stephanie

Stephanie James, PhD FASTMH
Senior Vice President, Science

APAR0000014739

b6

www.fnih.org

11400 Rockville Pike Suite 600, North Bethesda, MD 20852

From: Caroline Kurtz <[b6]>

Sent: Wednesday, April 22, 2020 6:58 PM

To: James, Stephanie (FNIH) [T] <[b6]>

Cc: Michaela Dankova <[b6]>

Subject: novel approach to COVID-19 vaccine

Dear Stephanie,

I am reaching out to you as a contact on the FNIH site for information regarding grant opportunities for a COVID-19 vaccine. I lead programs at a small Biopharma company in Cambridge MA called Synlogic Inc (www.synlogictx.com), and we are interested in applying for funding to support development of a vaccine for COVID-19 using our platform. We especially need support to test safety and efficacy of the vaccine in preclinical models under BSL3 conditions. Our proposal is as follows:

Synlogic Inc. proposes to develop a vaccine for the prevention of COVID19 utilizing its synthetic biology platform to engineer probiotic bacteria to express viral antigens and immune activators/adjuvants. This vaccine will be based on an engineered E. coli Nissle (EcN) bacterial strain that will express viral proteins from SARS-CoV2, the causative agent for COVID-19, and can be administered intranasally to induce protective immunity systemically and at mucosal surfaces. This vaccine can be manufactured in our GMP facilities to produce millions of doses from a single batch. As a lyophilized bacterial cell product, it is expected to have good room temperature stability.

We would be in preclinical development of this vaccine candidate, but already have an engineered E. coli Nissle strain currently in clinical trials for oncology, that can be rapidly adapted for this purpose. The grant would allow us to engineer the strain and test it in preclinical models to get a candidate for clinical studies. Our questions are:

1. Is this project of interest to FNIH? (we could provide an abstract if you need to read more detail to know)
2. Is grant funding available for small businesses?
3. Would a phone call facilitate determining level of interest for this work?
4. What is the process to apply?

Thanks very much for your help and if I should direct my inquiry elsewhere, please advise.

Sincerely,

Caroline Kurtz

Caroline Kurtz, PhD
SVP, Head of Portfolio Strategy and Product Development
Synlogic Inc
301 Binney Street, Suite 402
Cambridge MA, 02142

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/15/2020 1:24:54 PM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolberg]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Higgins, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfde4719d7ac48e4a60b2ecd1969a716-higginsl]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Agree, that is the name we have been using. Thanks, Rebecca

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:48 AM
To: Burklow, John (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis & All,

Another picky editorial comment. On the second slide, we probably need to revise the name of the second working group to "Therapeutics Clinical Working Group." At least that was the name that FNIH asked us to use when Ashley and I were proofing your JAMA Viewpoint article yesterday evening. If that change is okay with everyone, I can have Jill George modify the slide and resend.

Rebecca

From: Burklow, John (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 10:39 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi, Francis—

We have a policy, worked out with OGC, where we don't include company logos on the NIH website. That said, FNIH could certainly post them. We'll come up with a graphic that includes the partners, etc., for the NIH page.

Thanks,

John

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 10:18 AM

To: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

How about these two?

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 8:03 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,

Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis:

You mentioned that there are images in the presentations that we can use on the webpage, but those images seem very detailed and appear to contain confidential information to me. Would you let me know which particular image that you and David feel represents the overall program but doesn't give away too much information?

We're going to start building the page in draft today (not public).

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]

Sent: Wednesday, May 13, 2020 4:59 PM

To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thanks, all. This is great information. I can add the items from Francis and David to the strategic comms plan and will look for comments from Abbey on the webpage/plan.

Will FNIH reach out to the EC/WG members to ask permission for listing them on the website? We'd love to get this page up this week, if possible.

Best,
Renate

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 4:38 PM

To: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good points.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 4:19 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis: two other things that are possible and not already on your list below 1) the position paper from the ACTIV Vaccines WG on the issue of doing human challenge trials for Vaccines which I would hope would be ready for release by some time next week 2) a monoclonal antibodies master protocol, timing TBD (since we just received the charge this morning)
David

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 4:07 PM
To: Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi all,

I too want to say thanks to Renate for putting together this draft of the web page – it will be great to have something posted soon.

Building off of presentations to the Leadership Team/Exec Comm, we have a number of visuals that might be appropriate to include, and that would make the web site more pleasing to the eye.

I would be in favor of including the members of the working groups (it's a very impressive list) but only after asking their permission. It would also be good to designate the co-chairs of each of the Working Groups.

The Comms and Leg plan also looks good, though obviously there are uncertainties about the timing of various newsworthy events. In the not too distant future, I think we can imagine these developments:

- 1) Publication of the JAMA Viewpoint – Howard Bauchner has been moving this along at a very rapid pace, I wouldn't be surprised to see the publication emerge within the next week. Would that be a good moment to launch the web site?

- 2) Next week's planned summit, convened by ACTIV, on development of a master protocol(s) for monoclonal Abs – the meeting itself will be closed, but it might be possible to acknowledge that it's happening – as we did for the HEAL initiative a few times.
- 3) The launch of the anticoagulation four-arm trial, with leadership from NHLBI but under the ACTIV umbrella – I don't know exactly what the time table might be
- 4) The launch of the immunomodulator trial – which awaits working out the arrangements with the companies supplying the drugs, and then doing the match with the clinical trial networks that can make this work (through ACTT3)
- 5) The development and announcement of the harmonized master protocol for vaccines, with expectation that the first volunteers will be enrolled in the Ph II/III trials around July 1.

In the midst of all this, it looks like the US government is on the brink of announcing the joint HHS-DOD Manhattan Project 2, aka Operation Warp Speed, with Moncef Slaoui (former GSK) recruited to be the big kahuna, and a general from DoD as deputy. We will need to have materials ready to explain how that all fits with ACTIV. Jon Cohen's story has already confused the issue.

FC

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 3:24 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
 Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
 Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
 Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]
 Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]
 Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Renate,

I have looked at the NIH ACTIV webpage outline and communications and legislative strategy. Thank you for sending them.

The webpage outline is generally fine, Abbey will send you some specific comments. Please note that we have not made the names of the WG participants public in such a visible way. I have no concerns about this, although it appears that the NIH participants are more cautious about having their names out there.

On the communications and legislative strategy, it was very good to see that Carrie's shop is featured prominently. They do an outstanding job at putting together the summaries and technical descriptions of the activities of the PPPs, as they have done in AMP and HEAL.

You have identified some portions for FNIH input. Abbey will reach out directly to you to clarify exactly what you anticipate to be the FNIH role in this.

Thanks, Maria

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 2:43 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6] Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6] Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6] Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6] Schwetz, Tara (NIH/OD) [E]
[b6]
Subject: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good afternoon:

In the interest of time, I wanted to share the attached two items for both NIH and FNIH leadership review. Attached are:

- 1) Draft web content for a proposed NIH ACTIV web page:
 - Currently, the content is based primarily on publicly available information (mostly pulled from the release).
 - The only new content is the listing of the Executive Committee and Working Group members.
 - Having an ACTIV webpage will provide interested stakeholders with a central resource for ACTIV information, including releases, scientific papers, blogs, etc.; will point people to the scientific portal for submitting assets; and would allow us to provide status updates, as appropriate and as desired, on ACTIV developments.
 - This page can be expanded when we are ready to make more information public.
- 2) Draft ACTIV Communication and Legislative Strategy:
 - The strategy includes proposed tactics that could be developed in the near term, as well as longer lead items that we can prepare for now as we consider appropriate timing.

If it's helpful, we'd be happy to participate in a call to talk through these recommendations with you. We look forward to your feedback.

Best,
Renate

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: [b6]

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/14/2020 5:19:21 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Information

I don't think I know the answers. Can you circle back to Gary and ask?

From: Wholley, David (FNIH) [T] <b6>
Sent: Thursday, May 14, 2020 11:08 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Parker, Ashley (NIH/OD) [E]
Subject: RE: Information

How broadly can this be shared (the portal I assume is public, but the PP deck?) Can we assume Janet has seen it? And is the same as the ASPR/BARDA "tracker" or "dashboard" of clinical trials in progress we have been hearing about? Peter Stein has just been asking me about the latter.

From: Collins, Francis (NIH/OD) [E] <b6>
Sent: Thursday, May 14, 2020 6:47 AM
To: Disbrow, Gary (OS/ASPR/BARDA) <b6>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <b6>; Johnson, Robert (OS/ASPR/BARDA) <b6>; Lane, Cliff (NIH/NIAID) [E] <b6>; Wholley, David (FNIH) [T] <b6>; Tabak, Lawrence (NIH/OD) [E] <b6>; Parker, Ashley (NIH/OD) [E] <b6>
Subject: RE: Information

Many thanks, Gary. The discussion was really helpful, and I appreciate this follow up.

Best, Francis

<< File: 20200508 BARDA Medical Countermeasures Response - Portfolio V2.pptx >>

From: Disbrow, Gary (OS/ASPR/BARDA) <b6>
Sent: Thursday, May 14, 2020 4:10 AM
To: Collins, Francis (NIH/OD) [E] <b6>; Tabak, Lawrence (NIH/OD) [E] <b6>
Cc: Disbrow, Gary (OS/ASPR/BARDA) <b6>; Johnson, Robert (OS/ASPR/BARDA) <b6>
Subject: Information

Francis and Larry,

Thank you for the discussion last night. We have a long standing, collaborative relationship with several institutes at NIH and look forward to the collaboration with the ACTIV Partnership.

The URL for our BARDA website is below. The page changes every several seconds and one has the icon to view the portfolio. The link to the portfolio page can also be found lower down on the page below the newsroom link.

<https://www.medicalcountermeasures.gov/>

Attached is a deck showing our investments across vaccines, therapeutics, diagnostics, rapidly deployable capabilities and non-clinical and other support. There will be one update today, we are supporting AZ for development of SARS-CoV-2 specific monoclonal antibodies.

<< File: 20200508 BARDA Medical Countermeasures Response - Portfolio V2.pptx >>

Regards,

Gary

Gary L. Disbrow Ph.D.

Deputy Assistant Secretary

Director, Medical Countermeasure Programs

Biomedical Advanced Research and Development Authority

BARDA

Assistant Secretary for Preparedness and Response ASPR

Department of Health and Human Services

330 Independence Avenue, S.W. Room 640 G

Washington, D.C. 20201

Office: b6

Mobile:

Fax: 202-205-0873

email: b6

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Note to contractors: nothing in this e-mail is intended to constitute contractual direction or to impact cost, price, or schedule contained in the contract. If the contractor believes there is an impact, the contractor must disregard that portion of the communication and contact the Contracting Officer for direction

From: Kolberg, Rebecca (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=30071513C5A8433A98883FD78D360A91-KOLBERGR]
Sent: 5/14/2020 1:37:35 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Got it. This is very helpful, David. Just trying to bring the WG names in the Figure in line with the names of the WG names in the text.

RK

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Wednesday, May 13, 2020 9:36 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Santos, Michael (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

No Rebecca it should not. For the Preclinical Working Group is indeed dealing with preclinical issues regarding vaccines that the Vaccines WG is not dealing with, such as the appropriate animal models (if any) for preclinical vaccine testing and the appropriate in-vitro tests. They are doing this across both vaccines and therapeutics, which is why about a week ago Francis himself asked us to change the name from Tx – Preclinical to just Preclinical. Thanks, David

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 9:32 PM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

So, should the mention of vaccines be removed from the text of the Preclinical Working Group (Page 2, Column 1, Second Paragraph, Column 1)?

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 9:30 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Because the Vaccines Group is handling scientific issues that span both preclinical and clinical spaces, like immune enhancement.

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 9:24 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Just curious. If ACTIV has a Therapeutics Clinical Working Group, why is isn't the Vaccines Working Group called the Vaccines Clinical Working Group for parallel nomenclature? Or, alternatively, why not refer to the Therapeutics Clinical Working Group as the Therapeutics Working Group?

From: Parker, Ashley (NIH/OD) [E] { b6 }
Sent: Wednesday, May 13, 2020 9:19 PM
To: Kolberg, Rebecca (NIH/OD) [E] { b6 }
Subject: RE: JAMA Viewpoint on ACTIV: please review

The names of the working groups have varied since the initiation – here is how they are referred to most recently.

- Preclinical Working Group
- Therapeutics Clinical Working Group
- Clinical Trial Capacity Working Group
- Vaccines Working Group

Thanks for catching that!

From: Kolberg, Rebecca (NIH/OD) [E] { b6 }
Sent: Wednesday, May 13, 2020 9:00 PM
To: Parker, Ashley (NIH/OD) [E] { b6 }
Subject: RE: JAMA Viewpoint on ACTIV: please review

What are the official names of the Working Groups? Do you or David Wholley have a list? The text of this article says that the Preclinical Working Group covers both therapeutics and vaccines, so we can't really call it Preclinical Therapeutics Working Group in either the text or the figure.

From: Parker, Ashley (NIH/OD) [E] { b6 } >
Sent: Wednesday, May 13, 2020 8:57 PM
To: Collins, Francis (NIH/OD) [E] { b6 }; Kolberg, Rebecca (NIH/OD) [E] { b6 }
Subject: RE: JAMA Viewpoint on ACTIV: please review

This explains to renaming of the working groups in the figure. As Rebecca has indicated we will need to be consistent.

From: Collins, Francis (NIH/OD) [E] { b6 }
Sent: Wednesday, May 13, 2020 8:15 PM
To: Parker, Ashley (NIH/OD) [E] { b6 }; Kolberg, Rebecca (NIH/OD) [E] { b6 }
Subject: FW: JAMA Viewpoint on ACTIV: please review

From: Howard Bauchner { b6 }
Sent: Wednesday, May 13, 2020 5:25 PM
To: Stacy Christiansen { b6 }; Collins, Francis (NIH/OD) [E] { b6 }
Cc: Karen Bucher { b6 }
Subject: Re: JAMA Viewpoint on ACTIV: please review

Francis

Stacy is Managing Editor of JAMA and is working every day to get our content out. She leads our manuscript editing group.

Karen is head of graphics and redid your figure (everything at JAMA is redrawn).

Please let Karen know if you prefer a different look.

Comments on the text go to Stacy.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my [chats with authors](#)

From: Stacy Christiansen <[REDACTED] b6 [REDACTED]>
Date: Wednesday, May 13, 2020 at 4:22 PM
To: Francis Collins [REDACTED] b6 [REDACTED]
Cc: Howard Bauchner [REDACTED] b6 [REDACTED], Karen Bucher
[REDACTED] b6 [REDACTED]
Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,
Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

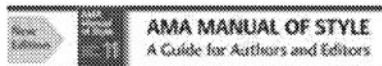
The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA
Managing Editor, *JAMA*
Chair, *AMA Manual of Style*



From: Kolberg, Rebecca (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=30071513C5A8433A98883FD78D360A91-KOLBERGR]
Sent: 5/13/2020 11:05:46 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Will do! My email box just dislodged a whole raft of emails that I received after 4:40 p.m.. If Renate could send the URL for the website, I'd be glad to insert.

From: Collins, Francis (NIH/OD) [E] [b6] >
Sent: Wednesday, May 13, 2020 5:48 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6] >
Cc: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6] Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

Can you give these galley proofs a very close read, and let me know if you find anything amiss?

Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

From: Stacy Christiansen [b6] >
Sent: Wednesday, May 13, 2020 5:22 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Howard Bauchner [b6]; Karen Bucher [b6]
Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,
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The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.
Thank you so much!

Best, Stacy
Stacy L. Christiansen, MA
Managing Editor, *JAMA*
Chair, *AMA Manual of Style*



From: Howard Bauchner [b6]
Sent: 5/12/2020 6:51:49 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Phil Fontanarosa [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: Viewpoint on ACTIV

Got it – perfect.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my [chats with authors](#)

From: Francis Collins [b6]
Date: Tuesday, May 12, 2020 at 1:45 PM
To: Howard Bauchner [b6]
Cc: Phil Fontanarosa [b6]; "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: RE: Viewpoint on ACTIV

[Warning External Email]

Yes, great idea, thanks for asking. See new version below and attached.

Best, Francis

We would like to acknowledge Ashley Parker, Rebecca Kolberg, and David Wholley for their help in preparation of this manuscript. We would also like to thank the leadership of AbbVie, Amgen, AstraZeneca, Bristol Myers Squibb, Eisai, Eli Lilly, Evotec, Gilead, GlaxoSmithKline, Johnson & Johnson, KSQ Therapeutics, Merck, Novartis, Pfizer, Roche, Sanofi, Takeda, and Vir. We also thank multiple NIH Institutes (especially NIAID), the FDA, BARDA, CDC, the European Medicines Agency, the Department of Defense, the Veterans Administration, and the Foundation for NIH for their commitment in engaging in this unprecedented partnership.

From: Howard Bauchner [b6]
Sent: Tuesday, May 12, 2020 7:17 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Phil Fontanarosa [b6]
Subject: RE: Viewpoint on ACTIV

Minor edits – can you name the companies – folks will want to know who they are. And would delete the word courage.

HCB

We would like to acknowledge Ashley Parker, Rebecca Kolberg, and David Wholley for their help in preparation of this manuscript. We would also like to thank the leadership of more than a dozen biopharmaceutical companies, INCLUDING CAN YOU NAME THE COMPANIES, several NIH Institutes (especially NIAID), the FDA, BARDA, CDC, the European Medicines Agency, the Department of Defense, the Veterans Administration, and the Foundation for NIH for their (PLEASE DELETE courage) commitment in engaging in this unprecedented partnership.”

Francis

From: Howard Bauchner [b6]
Sent: Monday, May 11, 2020 3:21 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Phil Fontanarosa [b6]; Stoffels, Paul [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Viewpoint on ACTIV

Should not be a problem – just send along the names and I will take care of it.

We would like to acknowledged the following individuals who are ...: xx, xx, xx,

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my chats with authors

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 2:19 PM
To: Howard Bauchner [b6]
Cc: Phil Fontanarosa [b6]; Stoffels, Paul [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Viewpoint on ACTIV

[Warning External Email]

Good point! Can we get you an Acknowledgement to squeeze in?

Francis

From: Howard Bauchner [b6]
Sent: Monday, May 11, 2020 10:24 AM
To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Phil Fontanarosa [REDACTED]; Stoffels, Paul [REDACTED]; Parker, Ashley (NIH/OD) [E] [REDACTED]

Subject: RE: Viewpoint on ACTIV

Francis/Paul

Thinking it would be helpful to name the folks from industry you have collaborated with at the end of the article – in additional information – suspect most readers will want to know who.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

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Listen to my [chats with authors](#)

From: Collins, Francis (NIH/OD) [E] [REDACTED]

Sent: Monday, May 11, 2020 9:03 AM

To: Howard Bauchner [REDACTED]

Cc: Phil Fontanarosa [REDACTED]; Stoffels, Paul [REDACTED]; Parker, Ashley (NIH/OD) [E] [REDACTED]

Subject: RE: Viewpoint on ACTIV

[Warning External Email]

Here you go. Many thanks for your very rapid response!!

Best, Francis

From: Howard Bauchner [REDACTED]

Sent: Sunday, May 10, 2020 1:47 PM

To: Collins, Francis (NIH/OD) [E] [REDACTED]

Cc: Phil Fontanarosa [REDACTED]

Subject: Re: Viewpoint on ACTIV

Francis – attached are our edits –

Just return a clean copy and one with track changes to Phil and me.

Stay healthy.

HCB

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Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

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From: Francis Collins [b6]
Date: Sunday, May 10, 2020 at 11:32 AM
To: Howard Bauchner [b6]
Cc: "Stoffels, Paul" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], Tony
Fauci [b6], "Burklow, John (NIH/OD) [E]" [b6], "Myles, Renate (NIH/OD)
[E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Kolberg, Rebecca
(NIH/OD) [E]" [b6], "Wolinetz, Carrie (NIH/OD) [E]" [b6], "Wholley,
David (FNIH) [T]" [b6], "Freire, Maria (FNIH) [T]" [b6]
Subject: Viewpoint on ACTIV

[Warning External Email]

Dear Howard,

On behalf of Paul Stoffels and myself, please see attached a Viewpoint on the ACTIV public-private partnership that we would like to have considered for publication in JAMA. Because of the rapidly moving events surrounding the COVID-19 pandemic, your offer to review this quickly is much appreciated.

I will serve as corresponding author.

Many thanks, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/12/2020 6:44:10 PM
To: Howard Bauchner [b6]
CC: Phil Fontanarosa [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
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Attachments: JAMA ACTIV Acknowledgements.docx

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Editor in Chief of JAMA and the JAMA Network

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Editor in Chief of JAMA and the JAMA Network

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Cc: Phil Fontanarosa [b6]; Stoffels, Paul [b6]; Parker, Ashley (NIH/OD) [E] [b6]
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Subject: Re: Viewpoint on ACTIV

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Editor in Chief of JAMA and the JAMA Network

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Subject: Viewpoint on ACTIV

[Warning External Email]

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APAR0000001551

I will serve as corresponding author.

Many thanks, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/12/2020 12:08:19 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Viewpoint on ACTIV

Ah, OK that's what I thought you might mean. Got it.

From: Collins, Francis (NIH/OD) [E] <b6>
Sent: Tuesday, May 12, 2020 8:06 AM
To: Wholley, David (FNIH) [T] <b6>
Cc: Parker, Ashley (NIH/OD) [E] <b6>
Subject: Re: Viewpoint on ACTIV

I'm actually considering the clock started for AMP at a Hever meeting a year before that

Sent from my iPhone

On May 12, 2020, at 7:28 AM, Wholley, David (FNIH) [T] <b6> wrote:

FYI, I don't know what BCG did for you before we came on the scene with AMP, but we "hired" them in February 2013 and they had ramped down by October 2013, which is included in the year I cited below. I think you could say "over a year" instead of "2 years" but up to you.

From: Collins, Francis (NIH/OD) [E] <b6>
Sent: Monday, May 11, 2020 9:15 PM
To: Wholley, David (FNIH) [T] <b6>; Parker, Ashley (NIH/OD) [E] <b6>
Cc: Stoffels, Paul [JJCUS] <b6>
Subject: RE: Viewpoint on ACTIV

Yep, I'm counting that long and drawn out process that BCG oversaw, which took at least another entire year.

From: Wholley, David (FNIH) [T] <b6>
Sent: Monday, May 11, 2020 1:53 PM
To: Parker, Ashley (NIH/OD) [E] <b6>; Collins, Francis (NIH/OD) [E] <b6>
Cc: Stoffels, Paul [JJCUS] <b6>
Subject: RE: Viewpoint on ACTIV

FYI, my experience with AMP was that FNIH was brought in to manage the design of the AMP partnership in February, 2013 and the partnership was announced in February 2014. I am aware there was a gestation period before the design phase where the idea of doing something like AMP was discussed at NIH and perhaps HEVER. I suppose that is what you are counting as two years?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 8:58 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Stoffels, Paul [JJCUS] [b6]
Subject: RE: Viewpoint on ACTIV

Hi Francis,

Please see the attached changes FNIH provided below in addition to the update on the number of identified networks by the clinical capacity WG – now “44”.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, May 11, 2020 8:12 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E]
[b6]
Cc: Stoffels, Paul [JJCUS] [b6]
Subject: RE: Viewpoint on ACTIV

Hi Ashley:

Yes, please remove “vaccines” from the Clinical Tx working group description.

In the vaccines description, In the vaccines section we suggest that “This includes development of a harmonized master protocol for adaptive trials of **three or more** vaccines” to “This includes development of a harmonized master protocol for adaptive trials of **multiple** vaccines.” I don’t think we want to hem ourselves in by saying 3 or more.

I have a call in to Karen Tountas to confirm the number of sites (38) mentioned in the Clinical Trial Capacity WG so I can get you the latest updated number. Those are the only changes from us.
David

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Sunday, May 10, 2020 7:01 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Stoffels, Paul [JJCUS] [b6]
Subject: RE: Viewpoint on ACTIV

Hi Francis,

Looks fine but would only flag a few minor items to be confirmed. David – could your team confirm the items below?

- **The Clinical Therapeutics Working Group:** “To help achieve these goals, the group has established a steering committee with relevant expertise and objectivity to set criteria for evaluating and ranking potential candidate therapies and vaccines submitted by industry partners.”

- Is the agreement to have the clinical Tx WG evaluate and rank “vaccines”? Only confirming considering I understood the vaccine group would prioritize vaccine candidates using special criteria?
- **The Vaccines Working Group:** “This includes development of a harmonized master protocol for adaptive trials of three or more vaccines...”
 - There were discussions over the weekend regarding the master protocol for vaccines – uncertain of the final decision. Individual harmonized protocols?

Thank you for the opportunity to review.
Ashley

From: Stoffels, Paul [JJCUS] [b6]
Sent: Sunday, May 10, 2020 2:32 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
Subject: Re: Viewpoint on ACTIV

All good. Please go ahead. Thanks for taking the lead. This is going to be a great partnership.

Have a bit of a relaxed sunday !

Paul

Verstuurd vanaf mijn iPad

Op 10 mei 2020 om 20:05 heeft Collins, Francis (NIH/OD) [E] [b6] het volgende geschreven:

Hi Paul,

I don't think I've ever seen a manuscript edited and returned in two hours! We must be working on something important.

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If we can get this back to JAMA today, that would be great.

Thanks, Francis

From: Howard Bauchner [b6]
Sent: Sunday, May 10, 2020 1:47 PM
To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Phil Fontanarosa [b6]

Subject: Re: Viewpoint on ACTIV

Francis – attached are our edits –

Just return a clean copy and one with track changes to Phil and me.

Stay healthy.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

Please respect the confidentiality of this email

Listen to my chats with authors

From: Francis Collins [b6]
Date: Sunday, May 10, 2020 at 11:32 AM
To: Howard Bauchner [b6]
Cc: "Stoffels, Paul" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], Tony Fauci [b6], "Burklow, John (NIH/OD) [E]" [b6], "Myles, Renate (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Kolberg, Rebecca (NIH/OD) [E]" [b6], "Wolinetz, Carrie (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Freire, Maria (FNIH) [T]" [b6]
Subject: Viewpoint on ACTIV

[Warning External Email]

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I will serve as corresponding author.

Many thanks, Francis

<JAMA ACTIV_050920 5-10-2020.docx>

<JAMA ACTIV Figure_050920.docx>

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/11/2020 7:19:28 PM
To: Howard Bauchner [b6]
CC: Phil Fontanarosa [b6]; Stoffels, Paul [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Viewpoint on ACTIV

Good point! Can we get you an Acknowledgement to squeeze in?

Francis

From: Howard Bauchner [b6]
Sent: Monday, May 11, 2020 10:24 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Phil Fontanarosa [b6]; Stoffels, Paul [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Viewpoint on ACTIV

Francis/Paul

Thinking it would be helpful to name the folks from industry you have collaborated with at the end of the article – in additional information – suspect most readers will want to know who.

HCB

Howard Bauchner, MD
Editor in Chief of JAMA and the JAMA Network

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Listen to my [chats with authors](#)

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 9:03 AM
To: Howard Bauchner [b6]
Cc: Phil Fontanarosa [b6]; Stoffels, Paul [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Viewpoint on ACTIV

[Warning External Email]
Here you go. Many thanks for your very rapid response!!

Best, Francis

From: Howard Bauchner <[b6]>
Sent: Sunday, May 10, 2020 1:47 PM
To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Phil Fontanarosa [b6]

Subject: Re: Viewpoint on ACTIV

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Date: Sunday, May 10, 2020 at 11:32 AM

To: Howard Bauchner [b6]

Cc: "Stoffels, Paul" [b6] >, "Tabak, Lawrence (NIH/OD) [E]" [b6], Tony
Fauci [b6], "Burklow, John (NIH/OD) [E]" [b6] >, "Myles, Renate (NIH/OD)
[E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Kolberg, Rebecca
(NIH/OD) [E]" [b6], "Wolinetz, Carrie (NIH/OD) [E]" [b6] >, "Wholley,
David (FNIH) [T]" [b6] >, "Freire, Maria (FNIH) [T]" [b6] >

Subject: Viewpoint on ACTIV

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I will serve as corresponding author.

Many thanks, Francis

From: Kolberg, Rebecca (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=30071513C5A8433A98883FD78D360A91-KOLBERGR]
Sent: 5/11/2020 4:18:04 PM
To: Kumar, SEEMA [JJCUS]; [b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Castillejos, Carlos [JJCUS] [CCastil6@its.jnj.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Draft JAMA article on ACTIV

Just an FYI that Dr. Collins submitted this manuscript to JAMA yesterday. No word yet on possible pub date.

From: Kumar, SEEMA [JJCUS]; [b6]
Sent: Friday, May 8, 2020 10:48 AM
To: Kolberg, Rebecca (NIH/OD) [E]; [b6]
Cc: Wholley, David (FNIH) [T]; [b6]; Castillejos, Carlos [JJCUS]; [b6]; Parker, Ashley (NIH/OD) [E]; [b6]
Subject: Re: Draft JAMA article on ACTIV

Hi Becky,

Long time no speak!! How are you? I am not sure if you remember me from the NIH Catalyst? Hope you are well and keeping safe.

I wanted to follow up with the team to see if you know when the JAMA piece would be published? Also who should I reach out to find out if NIH is planning a press release on the prioritization decisions on compounds selected from last week. I had heard from some of our internal partners that this was a possibility.

Many thanks!

Seema

From: "Stoffels, Paul [JJCUS]"; [b6]
Date: Thursday, May 7, 2020 at 3:53 AM
To: "Collins, Francis (NIH/OD) [E]"; [b6]
Cc: "Parker, Ashley (NIH/OD) [E]"; [b6]; "Kolberg, Rebecca (NIH/OD) [E]"; [b6]; "Wholley, David (FNIH) [T]"; [b6]; "Castillejos, Carlos [JJCUS]"; [b6]; Seema Kumar; [b6]
Subject: Re: Draft JAMA article on ACTIV

Dear Francis,

Please find enclosed my comments, mostly focused on positioning ACTIV in the international context of collaboration. Hope this will contribute to position ACTIV for global impact and collaboration.

Best regards,

Paul

From: Francis Collins [b6]
Date: Wednesday, 6 May 2020 at 03:16
To: "Stoffels, Paul [JJCUS]" [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6] "Kolberg, Rebecca (NIH/OD) [E]"
[b6], David Wholley [b6]
Subject: Draft JAMA article on ACTIV

Hi Paul,

Attached, with much help from Ashley Parker and Rebecca Kolberg of my staff, is a draft of the proposed ACTIV article for JAMA. I also attach a Figure that will explain the structure of the effort. Please have a look and let me know what you think.

I'm looking forward to the Leadership Group meeting on ACTIV tomorrow at 3:30 PM EDT, and glad you are co-chairing with me!

Best, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/11/2020 2:02:50 PM
To: Howard Bauchner [b6]
CC: Phil Fontanarosa [b6]; Stoffels, Paul [b6]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Viewpoint on ACTIV
Attachments: JAMA ACTIV Edits_051120.docx; JAMA ACTIV Clean_051120.docx; JAMA ACTIV Figure Final_051120.docx

Here you go. Many thanks for your very rapid response!!

Best, Francis

From: Howard Bauchner [b6]
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To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Phil Fontanarosa [b6]
Subject: Re: Viewpoint on ACTIV

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To: Howard Bauchner [b6]
Cc: "Stoffels, Paul" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], Tony Fauci [b6], "Burklow, John (NIH/OD) [E]" [b6], "Myles, Renate (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Kolberg, Rebecca (NIH/OD) [E]" [b6], "Wolinetz, Carrie (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Freire, Maria (FNIH) [T]" [b6]
Subject: Viewpoint on ACTIV

[Warning External Email]

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APAR0000001574

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Many thanks, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/11/2020 11:52:57 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Viewpoint on ACTIV

I sent it to my team last night and we will let you know asap this morning.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Sunday, May 10, 2020 7:15 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Viewpoint on ACTIV

All good points, Ashley. David, anything else to fix?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Sunday, May 10, 2020 7:05 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Stoffels, Paul [JJCUS] [b6]
Subject: RE: Viewpoint on ACTIV

Also, I thought we decided to delete "The ACTIV partnership has four working groups with subgroups devoted to specific issues. Each working group has about 16 members and there is substantial collaboration across working groups, especially on efforts to build the database and inventories" from the figure?

Thanks and apologies for the multiple emails.
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Sunday, May 10, 2020 7:01 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Stoffels, Paul [JJCUS] [b6]
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Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
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Cc: "Stoffels, Paul" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], Tony Fauci [b6], "Burklow, John (NIH/OD) [E]" [b6], "Myles, Renate (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Kolberg, Rebecca (NIH/OD) [E]" [b6], "Wolinetz, Carrie (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Freire, Maria (FNIH) [T]" [b6]
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Many thanks, Francis

<JAMA ACTIV_050920 5-10-2020.docx>

<JAMA ACTIV Figure_050920.docx>

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/10/2020 6:04:57 PM
To: Stoffels, Paul [b6]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: FW: Viewpoint on ACTIV
Attachments: JAMA ACTIV_050920 5-10-2020.docx; JAMA ACTIV Figure_050920.docx

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From: Francis Collins [b6]
Date: Sunday, May 10, 2020 at 11:32 AM

APAR0000001591

To: Howard Bauchner <[REDACTED] b6 [REDACTED]>
Cc: "Stoffels, Paul" <[REDACTED] b6 [REDACTED]>, "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]> Tony
Fauci <[REDACTED] b6 [REDACTED]>, "Burklow, John (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, "Myles, Renate (NIH/OD)
[E]" <[REDACTED] b6 [REDACTED]> "Parker, Ashley (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]> "Kolberg, Rebecca
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David (FNIH) [T]" <[REDACTED] b6 [REDACTED]> "Freire, Maria (FNIH) [T]" <[REDACTED] b6 [REDACTED]>
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Sent: 5/10/2020 4:35:10 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Stoffels, Paul [REDACTED] b6; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Fauci, Anthony (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=df38103d75134f658ae2d356f0396b94-afauci]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolberg]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: Re: Viewpoint on ACTIV

Got it. Hcb

Howard Bauchner, MD
Editor in Chief, JAMA and the JAMA Network

Please respect the confidentiality of this email

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Sunday, May 10, 2020 12:27:11 PM
To: Howard Bauchner [REDACTED] b6
Cc: Stoffels, Paul [REDACTED] b6; Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6; Fauci, Anthony (NIH/NIAID) [E] [REDACTED] b6; Burklow, John (NIH/OD) [E] [REDACTED] b6; Myles, Renate (NIH/OD) [E] [REDACTED] b6; Parker, Ashley (NIH/OD) [E] [REDACTED] b6; Kolberg, Rebecca (NIH/OD) [E] [REDACTED] b6; Wolinetz, Carrie (NIH/OD) [E] [REDACTED] b6; Wholley, David (FNIH) [T] [REDACTED] b6; Freire, Maria (FNIH) [T] [REDACTED] b6
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Many thanks, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/9/2020 8:11:28 PM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: RE: ACTIV Meeting with Vaccine Co-Chairs

Cliff and I have corresponded offline. I agree it does not make sense to invite the co-chairs now. Please however include Mike Santos of FNIH on this call. Thanks.

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Saturday, May 9, 2020 3:38 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]
Subject: Re: ACTIV Meeting with Vaccine Co-Chairs

Francis/Larry/David,

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The next step is to try and have a call tomorrow between 10:30 – 2:00 PM EDT to include the group on the NIAID call that just took place (names below); Peter Marks; Francis/Larry/David. While we did not talk one way or other about the ACTIV co-leads, I might not include them at this time due to the fact that there is no clear direction and Pfizer (Kathrin) has made it quite clear they do not want to work with NIH (NIAID).

If you are agreeable please let me know the best time for you and we will get a calendar invite out once I know your availability and that of Peter Marks.

Thanks,

Cliff

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2. John Mascola
3. Peter Gilbert (U. Washington statistician)
4. Larry Corey
5. Emily Erbelding
6. Carl Dieffenbach

7. Dean Follman (NIAID statistician)
8. Hugh Auchincloss
9. Hilary Marston
10. Cliff Lane

From: "Lane, Cliff (NIH/NIAID) [E]" <[REDACTED] b6 [REDACTED]>
Date: Saturday, May 9, 2020 at 8:47 AM
To: "Parker, Ashley (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, "Collins, Francis (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, Lawrence Tabak <[REDACTED] b6 [REDACTED]>, "Wholley, David (FNIH) [T]" <[REDACTED] b6 [REDACTED]>
Cc: "Wood, Gretchen (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Subject: Re: ACTIV Meeting with Vaccine Co-Chairs

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Peter Marks sent a fairly direct note to John Mascola (see below) that prompted Tony to call me. While I do not have all the incoming I think it is Peter responding to the notion that NIAID would be doing separate single product studies – at times at the same sites. I indicated to Tony I thought Peter's points were valid and consistent with some of the points raised on the NIAID call yesterday. Tony is planning to call Peter (hopefully prior to the 2:30 PM NIAID call today) to indicate that we (NIAID) want to work with him to resolve these issues. As soon as the 2:30 PM NIAID call is over I will get back to this string.

At that time, I anticipate it will be important to arrange the call noted by Ashley.

Cliff

"Dear John,

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Best Regards,
Peter"

From: "Parker, Ashley (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Date: Saturday, May 9, 2020 at 8:32 AM
To: "Collins, Francis (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>, Lawrence Tabak <[REDACTED] b6 [REDACTED]>, "Lane, Cliff (NIH/NIAID) [E]" <[REDACTED] b6 [REDACTED]>, "Wholley, David (FNIH) [T]" <[REDACTED] b6 [REDACTED]>
Cc: "Wood, Gretchen (NIH/OD) [E]" <[REDACTED] b6 [REDACTED]>
Subject: ACTIV Meeting with Vaccine Co-Chairs

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From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/9/2020 7:48:08 PM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
Subject: Re: ACTIV Meeting with Vaccine Co-Chairs

I am available at any time between 10:30-2. Just let me know what works best.
Larry

From: "Lane, Cliff (NIH/NIAID) [E]" [b6]
Date: Saturday, May 9, 2020 at 3:38 PM
To: "Parker, Ashley (NIH/OD) [E]" [b6], Francis Collins [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6]
Cc: "Wood, Gretchen (NIH/OD) [E]" [b6]
Subject: Re: ACTIV Meeting with Vaccine Co-Chairs

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Thanks,

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Date: Saturday, May 9, 2020 at 8:47 AM
To: "Parker, Ashley (NIH/OD) [E]" [b6], "Collins, Francis (NIH/OD) [E]" [b6], Lawrence Tabak [b6], "Wholley, David (FNIH) [T]" [b6]
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Sent: 5/9/2020 2:46:14 PM
To: Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: ACTIV Meeting with Vaccine Co-Chairs

Please keep Mike Santos copied on this string? If there is a call with the co-chairs he needs to be on it. Thanks

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Saturday, May 9, 2020 8:47 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]g>
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Cc: "Wood, Gretchen (NIH/OD) [E]" [b6]

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Thanks,
Ashley

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Sent: 5/8/2020 3:09:53 PM
To: Kumar, SEEMA [JJCUS] [b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Castillejos, Carlos [JJCUS] [CCastil6@its.jnj.com]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Draft JAMA article on ACTIV

Hi Seema,

Of course, I remember you--not only from the Catalyst, but from your early days at NCI, Johns Hopkins, and Whitehead/HGP! All if fine with my family, and I sure hope that yours keeping safe also.

We do not know the JAMA publication date, but I'll be sure to keep you in the loop for updates. As far as I know, it has not yet been submitted to JAMA editors and Francis is still revising the draft to reflect actions at Wednesday's ACTIV meeting. Regarding a possible NIH news release on the compound prioritization decisions, I haven't heard anything about that. Your best contacts probably would be Amanda Fine and Renate Myles who are cc'ed on this email.

All the best,

Rebecca

From: Kumar, SEEMA [JJCUS] [b6]
Sent: Friday, May 8, 2020 10:48 AM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Castillejos, Carlos [JJCUS] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Draft JAMA article on ACTIV

Hi Becky,

Long time no speak!! How are you? I am not sure if you remember me from the NIH Catalyst? Hope you are well and keeping safe.

I wanted to follow up with the team to see if you know when the JAMA piece would be published? Also who should I reach out to find out if NIH is planning a press release on the prioritization decisions on compounds selected from last week. I had heard from some of our internal partners that this was a possibility.

Many thanks!

Seema

From: "Stoffels, Paul [JJCUS]" [b6]
Date: Thursday, May 7, 2020 at 3:53 AM
To: "Collins, Francis (NIH/OD) [E]" [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6], "Kolberg, Rebecca (NIH/OD) [E]"

APAR0000001633

[b6], "Wholley, David (FNIH) [T]" [b6], "Castillejos, Carlos [JJCUS]"
[b6] Seema Kumar [b6]

Subject: Re: Draft JAMA article on ACTIV

Dear Francis,

Please find enclosed my comments, mostly focused on positioning ACTIV in the international context of collaboration. Hope this will contribute to position ACTIV for global impact and collaboration.

Best regards,

Paul

From: Francis Collins [b6]
Date: Wednesday, 6 May 2020 at 03:16
To: "Stoffels, Paul [JJCUS]" [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6], "Kolberg, Rebecca (NIH/OD) [E]"
[b6], David Wholley [b6]
Subject: Draft JAMA article on ACTIV

Hi Paul,

Attached, with much help from Ashley Parker and Rebecca Kolberg of my staff, is a draft of the proposed ACTIV article for JAMA. I also attach a Figure that will explain the structure of the effort. Please have a look and let me know what you think.

I'm looking forward to the Leadership Group meeting on ACTIV tomorrow at 3:30 PM EDT, and glad you are co-chairing with me!

Best, Francis

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/6/2020 1:27:44 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Gonzalez, Nina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3c2f486d]
Subject: FW: ACTIV Response Partnership Leadership Team Meeting #3
Attachments: ACTIV Partnership Leadership Team Meeting 20200505_draft attendee and agenda slides.pptx

fyi

From: Wholley, David (FNIH) [T]
Sent: Tuesday, May 5, 2020 9:27 PM
To: Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

Sorry, Nancy, it is the meeting we have been having every other Wednesday since April 3 with the leadership of all the partners. We are responding to your point made today on our Vx Working Group call (and perhaps earlier, sorry if that is the case) that CDC needs to be included in ACTIV governance. Attached is the latest on participants and agenda. We thought you'd be the best representative for CDC at this meeting given your role and your participation to date in ACTIV, but if you have someone else you think should represent the agency please let me know. N.B., as marked these are clearly in draft form.

David

From: Messonnier, Nancy (CDC/DDID/NCIRD/OD) [b6]
Sent: Tuesday, May 5, 2020 4:52 PM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

Sorry – I'm not sure what meeting this is? Is there an agenda?
Nancy

*Nancy Messonnier, MD
Director
National Center for Immunization and Respiratory Diseases
DDID, CDC*

-----Original Appointment-----

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 4:48 PM
To: Wholley, David (FNIH) [T]; Messonnier, Nancy (CDC/DDID/NCIRD/OD)
Subject: ACTIV Response Partnership Leadership Team Meeting #3
When: Wednesday, May 6, 2020 3:30 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us/j/> [b6]

Join Zoom Meeting

APAR0000001693

<https://fnih.zoom.us/j/> **b6**

Meeting ID: **b6**

Password: **b6**

One tap mobile

b6 US (Germantown)
US (Chicago)

Dial by your location

b6 US (Germantown)
US (Chicago)
US (New York)
US (Houston)
US (San Jose)
US (San Jose)
US (Tacoma)

Meeting ID: **b6**

Password: **b6**

Find your local number: <https://fnih.zoom.us> **b6**

From: Kolberg, Rebecca (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=30071513C5A8433A98883FD78D360A91-KOLBERGR]
Sent: 5/5/2020 5:13:40 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: Need help on a JAMA article on ACTIV

Ashley,

I'm in the middle of editing another time-sensitive document right now, so will need keep this brief. Do you have all the info you need right now to fill out all the gaps/update the deliverable times in the draft? If so, I recommend that you go ahead and revise the text (using EditTrack) in ways that address the need for updates/fill in the info gaps/answer queries. If you get those revisions done before COB, I'd be happy to give your modified version a quick scan. If not, I recommend sending your modified version directly to FC tonight per his request.

Rebecca

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 12:41 PM
To: Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: RE: Need help on a JAMA article on ACTIV

Hi Rebecca,

I am working through this now and was planning to share with you within the next hour or so before sending to FC tonight. For the questions you've raised in the draft, did you not want me to share this with you before it goes to FC?

I will attached the draft figure and include the additional reference you've provided below.

For the table: there are concerns about sharing this information publicly and I think this will be discussed with the leadership group tomorrow.

Thank you,
Ashley

From: Kolberg, Rebecca (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 12:32 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: FW: Need help on a JAMA article on ACTIV

Hi Ashley,

Just a few follow-up items for the modified version of the JAMA draft that you'll be sending to FC for his review tonight:

Figure. Attached is a draft Figure for FC's review. It is in JAMA's figure style and is adapted from the slide that FC plans to use at the Senate HELP Hearing. Please keep this as a separate file, per JAMA's instructions to authors.

Possible eTable. Once Jill and I receive from you the "short list" of potential COVID-19 therapies proposed for rapid clinical testing, we could create a Table that JAMA editors would likely designate as an eTable for inclusion in

Supplementary materials. If we don't receive that info in time to make the Table today, we can work on it tomorrow and send to FC for his review separately.

References. The Science Perspectives article that FC attached to his email this morning should be cited as a reference in the sentence below, as well as added as citation #4 to the References list at the end of the draft. Don't worry about the style of the reference right now... just insert the authors, title, and put publication TBD.

Sentence: **The Vaccines Working Group** will build a collaborative framework to share insights into natural immunity and vaccine candidate-induced immune response [4].

Hope this helps!

Rebecca

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Tuesday, May 5, 2020 7:15 AM

To: Kolberg, Rebecca (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] <[b6]>

Cc: Burklow, John (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]; Tabak,

Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]

Subject: FW: Need help on a JAMA article on ACTIV

Hi Rebecca,

Thanks for this very nice draft. Since Ashley has already seen a draft of the slides for tomorrow, I'm hoping she can provide the needed updates now. Ashley, can you take a crack at that, and then send me a modified version for me to look at tonight?

I'm also attaching a close-to-final draft of an article on COVID vaccine strategy that will appear next week in the NEJM. It mentions ACTIV rather prominently, and needs to be cross referenced.

FC

From: Kolberg, Rebecca (NIH/OD) [E] [b6]

Sent: Monday, May 4, 2020 6:25 PM

To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; George,

Jill (NIH/OD) [E] [b6]

Subject: RE: Need help on a JAMA article on ACTIV

Hi Francis,

Attached for your review is a draft of your JAMA article. Don't know if you want to look it over now, or if you'd rather wait for me to revise/update when Ashley or someone else sends me over updates from the Working Group meetings on Wednesday. Makes no difference to me!

In addition to the two key locations where you've noted that updates will be needed, there are a few other "late April" and "early May" mentions of deliverables throughout that we will need to address, probably after the WG meeting. Jill will adapt your second ACTIV slide from the Senate hearing for use as Figure 1 and I'll write a caption. If space allows, we might also propose a Table of the short list of the most promising treatments proposed by the Clinical Therapeutics Working Group.

Thanks,

Rebecca

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Sunday, May 3, 2020 4:26 PM

To: Kolberg, Rebecca (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]

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Attached is a copy of the e-mail from Howard Bauchner where he offers 1400-1500 words and a Figure.

Also attached is an outline – the beginning and end parts are from me, the middle parts from Ashley. Already at 1371 words, I recognize that some details will need to be dropped.

Also attached is a figure that could be used to explain the structure of ACTIV.

Have a look and let me know what you need to proceed. I'd love to get this submitted this week.

Tx, Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/5/2020 2:16:15 PM
To: Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolbergr]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Science or NEJM?

Sorry, that was a brain glitch. We originally sent it to NEJM and they rejected it. Science loved it.

FC

From: Kolberg, Rebecca (NIH/OD) [E] { b6 }
Sent: Tuesday, May 5, 2020 10:04 AM
To: Collins, Francis (NIH/OD) [E] { b6 }
Cc: Burklow, John (NIH/OD) [E] { b6 }; George, Jill (NIH/OD) [E] { b6 }; Tabak, Lawrence (NIH/OD) [E] { b6 }; Wholley, David (FNIH) [T] { b6 }; Parker, Ashley (NIH/OD) [E] { b6 }
Subject: Science or NEJM?

Hi Francis,

The galley proof that you sent re vaccine strategy is for a co-authored article by you, Fauci, and others in Science, not NEJM. Just wanted to doublecheck that was indeed the article that you'd like to reference in the JAMA piece. No rush!
Thanks,
Rebecca

From: Collins, Francis (NIH/OD) [E] { b6 }
Sent: Tuesday, May 5, 2020 7:15 AM
To: Kolberg, Rebecca (NIH/OD) [E] { b6 }; Parker, Ashley (NIH/OD) [E] { b6 }
Cc: Burklow, John (NIH/OD) [E] { b6 }; George, Jill (NIH/OD) [E] { b6 }; Tabak, Lawrence (NIH/OD) [E] { b6 }; Wholley, David (FNIH) [T] { b6 }
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Also attached is a figure that could be used to explain the structure of ACTIV.

Have a look and let me know what you need to proceed. I'd love to get this submitted this week.

Tx, Francis

APAR0000001715

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/5/2020 1:50:37 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: I/C directors that will be on Leadership call

Exceptions being Fauci, Gibbons, and Koroshetz, since they have ACTIV roles.

From: Collins, Francis (NIH/OD) [E]
Sent: Tuesday, May 5, 2020 9:49 AM
To: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: I/C directors that will be on Leadership call

Got it. I will say something at the beginning of the meeting to welcome them and make it clear they are there to listen. If someone forgets, I will try to diplomatically shut them down.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 9:06 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: I/C directors that will be on Leadership call

One of the questions (really an FYI) I did not get to on this morning's call is that so far we have over 50 NIH attendees signed up for the Leadership Team call tomorrow. I know you have told them they are in "listen mode only" but wanted to make sure you know there is nothing in Zoom that allows you to control or prespecify a class of attendees as "listen mode only." Essentially if they start to talk, Joe Menetski can mute them. But that is it. I wanted to make sure you know that and are comfortable with that fact.

David

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/5/2020 10:13:46 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

As long as they are listen only, I think this can only help with our ACTIV-NIH connectivity.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 8:12 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

We are not just getting Institute Directors, but half of NIH. Is that the intention?

From: Lankford, David (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 5:59 PM
To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Hello – I would like to listen to the Leadership Group this Wednesday. Thanks,

David W. Lankford
NIH Legal Advisor
Office of the General Counsel
Public Health Division, NIH Branch
NIH Building 31, Room 2B-50
Bethesda, MD 20892-2111
Telephone: [b6]
Fax:
E-Mail:

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed, or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution, or copying is strictly prohibited. If you think you have received this e-mail message in error, please notify the sender immediately.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 11:18 AM
To: ICDDIR-L@LIST.NIH.GOV
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Dear Colleagues,

As you may be aware, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership has been moving forward rapidly to address the global pandemic. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working

APAR0000001723

groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines.

Although some ICs have representatives participating in the working groups, we recognize there is a need to keep everyone looped in to the various activities and progress of the partnership, particularly in view of all of the concurrent IC projects about COVID-19. The ACTIV working groups will be delivering their second report to the **ACTIV Leadership Group on Wednesday, May 6, from 3:30-5:00pm**. I am writing to invite the ICDs to listen-in on this meeting. There will be a lot to cover during the meeting and the members of the Leadership Group will be asking the questions. But to give a chance for us NIHers to discuss what has been presented, I am scheduling a separate ICD call for 5:05-5:30pm, immediately following the ACTIV leadership meeting.

If you are available to take part, please send your responses to David Wholley and Cheryl Melencio of FNIH (cc'd here) by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and the ICD follow-up call.

Best regards,
Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/4/2020 5:51:12 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: BARDA Blog Mentions ACTIV - Is this OK?

No problem, this is fine.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 12:59 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Meltzer, Abbey (FNIH) [T] [b6]; Burklow, John (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
[b6]

Subject: FW: BARDA Blog Mentions ACTIV - Is this OK?

Importance: High

I don't see anything wrong with this but want to make sure it is OK, can you please let me know?

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 10:17 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: BARDA Blog Mentions ACTIV - Is this OK?
Importance: High

Hi David,

See attached and below. BARDA would like to mention ACTIV in a COVID related blog post. Is this okay?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

APAR0000001731

Direct: [b6] Mobile: [b6]

From: Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]
Sent: Monday, May 4, 2020 9:59 AM
To: Jarrett, Elizabeth (OS/ASPR/OEA) [b6]; Simpson, Steven (OS/ASPR/BARDA) (CTR) [b6]
Cc: Sciarretta, Kimberly (OS/ASPR/BARDA) [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: For Review: Sepsis Blog

This is fine with me. I am copying Stacey Adam at FNIH to make sure that the mention of ACTIV is not going to cause anyone concern. Please stand by.

Stacey, this is one of two blogs and the only one that mentions ACTIV and the mention is utterly oblique. I do not think it's an issue, but I want to make sure that BARDA is not breaking protocol by mentioning that BARDA is contributing expertise to ACTIV.

Tim

Timothy G. Buchman, PhD, MD
Senior Advisor
IPA to the DRiVe (Division of Research, Innovation and Ventures)
Biomedical Advanced Research and Development Authority (BARDA)
Office of Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (HHS)
Thomas P. O'Neill, Jr. Federal Building (FOB8)
200 C St SW
Washington, DC 20024
Cell: [b6]
Email: [b6]

"Note: This email is intended to provide information and is not to be taken as a directive. If the recipient(s) believe(s) the information provided herein may be construed as a directive, the recipient(s) should disregard that portion of the email."

From: Jarrett, Elizabeth (OS/ASPR/OEA) [b6]
Sent: Monday, May 4, 2020 9:33 AM
To: Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Simpson, Steven (OS/ASPR/BARDA) (CTR) [b6]
Subject: FW: For Review: Sepsis Blog

Hi Tim and Steve,

Just a ping on the email that I sent Friday night. We split apart your blog on sepsis into a couple of parts and we would like to publish this one later this week as part of Public Service Recognition Week.

Thoughts on the attached and can we list you as authors?

Thanks,
Elizabeth

From: Jarrett, Elizabeth (OS/ASPR/OEA)

Sent: Thursday, April 30, 2020 6:16 PM

To: Buchman, Tim (OS/ASPR/BARDA) (CTR) [b6]; Simpson, Steven (OS/ASPR/BARDA) (CTR)

[b6]

Cc: Kane, Elleen (OS/ASPR/OEA) [b6]

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Sent: 5/3/2020 1:39:31 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: ACTIV External Communications Opportunity

Hi Francis. Great! I'll work with the Blackrock folks.

We are in GREAT need of a communications strategy. This has been raised before. Linking it to the Leadership Group meetings makes sense. Yes, let's discuss on Monday.

As David will report on that call, the FNIH has put together an A team of expert lawyers to help us navigate legal issues that may arise. Here too we should put together a communications A team, which would include John, Abbey, selected partners' Comms folks and perhaps call in some support from agency experts.

We need to figure out the key audiences and then craft strategies for each. There is a need for internal and external strategies. Internal to NIH, to make sure all ICs are up to speed and to partner company staff and leadership so that the right and left hands are in sync. The external strategy would be broader, of course - academics to get them excited and eager to be involved, the Hill to garner their support, etc.

One potential outreach, among more traditional ones, is to create a social media tool kit, with key, pre-drafted messages for Twitter, Facebook and LinkedIn that gets amplified by all partners. Another may be to get some video "interviews", like Blackrock and Keystone Symposium (they have asked what they can do to help). However, because of time demands, we will need to be very disciplined and strategic.

Let me noodle on this, M.

From: "Collins, Francis (NIH/OD) [E]" <[REDACTED]>
Date: Saturday, May 2, 2020 at 7:48:06 PM
To: "Freire, Maria (FNIH) [T]" <[REDACTED]>
Cc: "Burklow, John (NIH/OD) [E]" <[REDACTED]>, "Tabak, Lawrence (NIH/OD) [E]" <[REDACTED]>, "Wholley, David (FNIH) [T]" <[REDACTED]>, "Parker, Ashley (NIH/OD) [E]" <[REDACTED]>
Subject: RE: ACTIV External Communications Opportunity

Hi Maria,

I don't know BAI and I'll have to trust the information from you and John about its reach, but if you think it's worth it, I'd be up for this kind of a fireside chat.

On a highly related note, we had a very significant Zoom meeting this afternoon with the ACTIV vaccines co-chairs – Doug Lowy and Kathrin Jensen. Tony Fauci, John Mascola, and Cliff Lane joined the call to outline the potential of a master protocol that could compare multiple vaccine programs in a rapidly enrolling Phase II/III trial, and could start as soon as July 1. Yes, I said July 1.

Doug Lowy noted at the end of the call that there are a great many things going on with ACTIV that are not widely known by the public or the scientific community – it's time to implement a communications strategy.

One part of that might be the ACTIV article for JAMA that Paul Stoffels and I are co-authoring (he has agreed). I am working on that this weekend, starting from Ashley's draft. But another mechanism for ongoing public disclosure would be to put out some kind of communication every two weeks, timed to follow the Leadership meetings. David and I thought that made a lot of sense. Such a communication would need to involve the capable comms shops at NIH and FNIH, but also the comms shops of the other partners (including industry). Maybe we can talk about this on Monday at our War Room meeting?

FC

From: Freire, Maria (FNIH) [T] [b6]
Sent: Saturday, May 2, 2020 3:39 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]
Subject: ACTIV External Communications Opportunity

Francis,

Russ Steenberg, is a member of our Board and Managing Director and Global Head of BlackRock Private Equity Partners (PEP), within BlackRock Alternative Investors (BAI). BAI has a forum that is broadcast to clients, investors and Blackrock staff all over the world.

A few weeks ago, when ACTIV was launched, Russ approached me to see if you would be willing to do a "fireside" chat (live or taped) to be broadcast as part of their coronavirus education to large audiences. My sense is that the time is right for you to do something like this – in mid-may – to get visibility for ACTIV and to firmly plant the ACTIV "flag" with a broader audience. There is a lot of noise and press out there for other initiatives, so this may be a good communications tool for you.

I reached out to John, copied here, last night to get his sense and he is supportive. BAI would produce and support this piece. Please let me know if this is of any interest.

Best, M.

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/29/2020 7:39:47 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: BIO Analysis of COVID-19 Pipeline by category

Yes, Francis, you can tell Jim that we connected last week with Danielle Friend and Cartier Esham from BIO and gave them a briefing on what we are doing with ACTIV. They shared information on BIO's inventory in return and we included their list, particularly the anti-virals, into the very first pass of our prioritization process.

David

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, April 29, 2020 12:17 PM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Cc: Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: BIO Analysis of COVID-19 Pipeline by category

Hi David and Stacey,

See message and attachment. I know you reached out to BIO earlier but did the Clinical Therapeutics WG already have access to BIO's analysis? It looks interesting.

FC

From: James C. Greenwood [b6]
Sent: Wednesday, April 29, 2020 12:12 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: McManus, Ayanna (NIH/OD) [E] [b6]; Karen V. Cologne [b6]; Cartier Esham [b6]
Subject: BIO Analysis of COVID-19 Pipeline by category

Dear Francis,

I read with interest your recent announcement of the ACTIV public-private partnership on accelerating COVID-19 treatments and vaccines – a subject that BIO has been intensely focused

on over the past two months. In particular, BIO is working with our broad base of companies and several expert consultants to identify the most significant likely bottlenecks to speedy clinical development and manufacturing scale-up for such products, as well as the capacities and resources that exist throughout the sector to solve those anticipated problems before they slow us down. As this project quickly progresses, we would be pleased to collaborate with NIH in terms of data sharing and execution of solutions if that is something of interest to you.

BIO also has been focused on helping government and NGO funding agencies better understand the unprecedented and rapidly growing pipeline of potential treatments and vaccines for COVID-19. We have more than 100 companies working on 300+ development programs, covering a wide range of potential approaches and technologies. To assist funders with a strategic review of this pipeline, we put together the attached slide deck summarizing the analysis done by our BIO Industry Analysis team, and explaining how this categorization and approach could aid the strategic and speedy review of funding proposals being made to government and other partners. We believe this information also could assist with ACTIV's strategic review and prioritization of potential assets. The Tracker that I refer to in these slides will be available soon on our BIO website and will be updated weekly.

Our goal is to be helpful to both the federal government and our member companies who wish to bring their innovative technologies to bear on solving this crisis. We stand ready to support any requests for assistance that you or your teams may have. Please feel free to reach out with any questions or comments.

Sincerely,

Jim Greenwood

Hon. James C. Greenwood
President and CEO
Biotechnology Innovation Organization (BIO)
Member of Congress, 1993-2005

1201 Maryland Avenue, SW – Suite 900
Washington, DC 20024

T b6

F +1.202.488.6307

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/30/2020 1:55:44 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV

Thanks!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 9:53 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV

Thanks, David! You have an awesome team!

Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 9:35 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV

Additional contact information (beyond email) if you ever need it:

Home office: [b6]
Cell phone: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 8:33 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Time Sensitive Question from Dr. Collins on ACTIV

Our legislative office needs this information for Dr. Collins ASAP – can you please acknowledge receipt of this request?

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, April 30, 2020 8:00 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: Time Sensitive Question from Dr. Collins on ACTIV

Good morning David,

As you know, Francis has his briefing with the Congress this morning and needs an answer to the question below ASAP. I'm looping in Stacey and Karen as well.

Thank you,

APAR0000001795

Ashley

From: Berkson, Laura (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 7:53 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]
Subject: question from FC on ACTIV

Hi Ashley,

As you know, Dr. Collins is briefing E&C committee members today on NIH's COVID-19 activities. When reviewing his prep materials, he asked the following question:

What's the representation of minority communities in the ACTIV clinical trials capacity working group inventory? Find this out from David Wholley/Stacey Adam

Since I know you've been working closely with FNIH on this, would you be able to help us get the answer? Let me know if it would be easier for us to reach out to them directly.

Best,
Laura

From: Lane, Cliff (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2D7E368A3137473BBCE161547A82F2DE-CLANE]
Sent: 4/29/2020 4:33:10 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: BIO Analysis of COVID-19 Pipeline by category

Just saw the below from Politico:

By [SARAH OWERMOHLE](#)

04/29/2020 11:43 AM EDT

Updated: 04/29/2020 11:55 AM EDT

A senior official at the Food and Drug Administration has emerged as the Trump administration's unofficial vaccine czar after the abrupt ouster of the scientist leading the multibillion federal effort to develop coronavirus treatments, according to three current and former health department officials.

Peter Marks trained as a cancer doctor and now directs the FDA office that oversees the approval of vaccines and gene therapies. HHS has increasingly positioned the quiet, trusted FDA official as an informal adviser to the Biomedical Advanced Research and Development Authority and other agencies on vaccine development.

Giving Marks, who a senior HHS official called "a world-class expert" on vaccines, a more prominent role could ease fears that the recent shakeup at BARDA could slow progress against the pandemic.

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Wednesday, April 29, 2020 at 12:16 PM
To: "Wholley, David (FNIH) [T]" [b6], "Adam, Stacey (FNIH) [T]" [b6]
Cc: "Austin, Christopher (NIH/NCATS) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], Lawrence Tabak [b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: BIO Analysis of COVID-19 Pipeline by category

Hi David and Stacey,

See message and attachment. I know you reached out to BIO earlier but did the Clinical Therapeutics WG already have access to BIO's analysis? It looks interesting.

FC

From: James C. Greenwood [b6]
Sent: Wednesday, April 29, 2020 12:12 PM
To: Collins, Francis (NIH/OD) [E]; [b6]
Cc: McManus, Ayanna (NIH/OD) [E]; [b6]; Karen V. Cologne [b6]; Cartier Esham [b6]
Subject: BIO Analysis of COVID-19 Pipeline by category

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Sincerely,

Jim Greenwood

Hon. James C. Greenwood
President and CEO
Biotechnology Innovation Organization (BIO)
Member of Congress, 1993-2005

1201 Maryland Avenue, SW – Suite 900
Washington, DC 20024

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F +1.202.488.6307

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From: Lane, Cliff (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2D7E368A3137473BBCE161547A82F2DE-CLANE]
Sent: 4/29/2020 4:00:15 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: Re: DoD Representatives

I am not aware of specific examples of clinical trials (of the type we are talking about) that are conducted by the DoD all over the world and are distinct from what NIAID is doing with USU. To clarify, we do not run CTs for USAMRIID; we fund a clinical trials network at the Uniformed Services University. The USU effort is led by CAPT Burgess and I think he would be a good person from a Team 2 to 3 cross-over perspective.

On 4/29/20, 11:42 AM, "Wholley, David (FNIH) [T]" [b6] wrote:

Thoughts?

-----Original Message-----

From: Tountas, Karen (FNIH) [T] [b6]
Sent: Wednesday, April 29, 2020 5:52 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: DoD Representatives

No rep for the CT Capacity WG? There are a number of folks on this WG who think the DoD has a lot to offer. I know you told us that NIAID claims to run their CTs for USAMRIID, but the DoD does a lot more than just infectious disease research, and conducts CTs all over the world.

K

-----Original Message-----

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, April 28, 2020 8:28 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: DoD Representatives

Cheryl,

When you get a chance tomorrow can you please draft invitation emails from Francis to each of these folks with appropriate addresses and send them to me? We can just model them on the template for the former invitations. Once I have reviewed I will send to FC so he can get them out. PS, I think we will need to get their titles for the rosters, as well as Dertzbaugh's full name, title, and email in case he subs for BG Talley on the Leadership Team calls.

Thanks much! David

-----Original Message-----

From: Lane, Cliff (NIH/NIAID) [E] [b6]
Sent: Tuesday, April 28, 2020 4:26 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T]
Subject: DoD Representatives

BG Talley concurs with the following nominees to support the ACTIV initiative:

Executive Group: BG Talley (Dr. Dertzbaugh backup), [b6]

Preclinical: Dr. Louise Pitt, USAMRIID, [b6]

Clinical: CAPT Tim Burgess, USUHS, [b6]

Vaccines: Dr. Nelson Michael, WRAIR, b6

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/28/2020 2:04:09 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: ACTIV background slides

Deal.

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, April 28, 2020 9:51 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: RE: ACTIV background slides

Please have Hilary to contact me directly.

Thank you,
Ashley

-----Original Message-----

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, April 28, 2020 9:49 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: ACTIV background slides

Hi Ashley--How would you like this handled?

-----Original Message-----

From: Marston, Hilary (NIH/NIAID) [E] [b6]
Sent: Tuesday, April 28, 2020 9:24 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: ACTIV background slides

David do you have any ACTIV overview slides handy? For a lay audience that is new to the PPP but savvy re COVID

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/27/2020 7:47:07 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: Public-private research collaboration

Victoria Davey of the VA's Public Health office joined the Clinical Trial Capacity Working Group calls last week.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, April 27, 2020 12:41 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: FW: Public-private research collaboration
Importance: High

What have we already done to incorporate VA into ACTIV?
FC

From: Clancy, Carolyn [b6]
Sent: Monday, April 27, 2020 9:02 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: Public-private research collaboration
Importance: High

Francis,

I read about the initiative / collaboration being led under the auspices of FNIH.

In the spirit of 'we're from the government and here to help', I am writing to express my team's enthusiasm for being a vital participant (we do have 170 medical centers and close to 9 million patients enrolled).

We are collaborating now with NIAID and others – and I am most excited to report that Dr. Ramoni has driven a year long initiative to streamline VA participation in clinical trials.

Many thanks in advance for your consideration.

Hope you and your loved ones are safe and in good health.

Carolyn. – personal cell [b6]

Carolyn M Clancy, MD
Assistant Undersecretary for Health
Discovery, Education and Affiliated Networks
Department of Veterans Affairs
810 Vermont Ave NW

APAR0000001836

Washington, DC 20420

Assistant: Alicia Bates

b6

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 1/22/2021 3:46:52 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: FW: Ivermectin trial [b4]

FYI. It's good to see PCORnet is thinking actively about the light touch platform for outpatient oral therapeutics. I will follow up about RWE.

FC

From: Josie Briggs [b6]
Sent: Friday, January 22, 2021 10:19 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Josie Briggs [b6]
Subject: RE: Ivermectin trial [b4]

The PCORnet team agrees – and is in active discussion about creating a platform trial for simple 'light touch' – ie largely virtual – trials on small molecules for early COVID. Janet W. has been part of those conversations.

Another idea has surfaced in conversations between All of Us, NCATS N3C and PCORnet (ie Josh, myself, Joni Rutter, Mike Kurilla) . A possible cooperative venture to develop RWE about impact of viral variants on vaccine efficacy. If your schedule permits – a brief conversation?
I can make an opening whenever is good for you.

To: Josie Briggs [b6]
Subject: RE: Ivermectin trial [b4]

Discussed ivermectin with the ACTIV War Room team this morning. General sense is that the [b4] study is not the end of the story, and other well designed trials are still needed. So please keep considering this for PCORnet.

Francis

From: Josie Briggs [b6]
Sent: Thursday, January 21, 2021 3:05 PM

To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: Ivermectin trial [b4]

Thanks for sharing this.

A largish fluvoxamine trial NCT04668950 has recently been launched (dec 20. '20) by Eric Lenze – a psychiatrist at Wash U, who is the author of the JAMA preliminary report. JAMA 2020 324 2292

He is funded by PCORI for other work. We are looking into how it is going. Also the PCORnet team met with the ACTIV group again on last Tuesday. Still exploring (and a bit uncertain) whether there are worthwhile drug studies waiting to be done. Relieved in a way if ivermectin is off the list.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, January 21, 2021 6:48 AM
To: Josie Briggs [b6]
Subject: Ivermectin trial [b4]

Hi Josie,

Thanks for talking with me last weekend about a possible PCORnet outpatient trial for ivermectin and fluvoxamine. New info has just been obtained about an ivermectin [b4] – see below. This is confidential. I'm trying to get more details, but this obviously has high relevance! Janet Woodcock is fully aware.

Francis

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, January 20, 2021 9:03 PM
To: Woodcock, Janet (FDA/CDER) [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Chen, Helen <qingchen@deloitte.com>; Appell, Evan <eappell@deloitte.com>; Read, Sarah (NIH/NIAID) [E] [b6]; Eric Hughes [b6]
Subject: Update on Ivermectin Discussion [b4]

Dear Janet, Cliff and David,

I wanted to reach out to let you know that the conversation [b4] of ivermectin today. Provided what the ACTIV review panel for both immunomodulators and antivirals felt was compelling evidence for not pursuing a study with this agent. While the data is not published, it has been submitted to JAMA for review, and is summarized below. With this information and the assessment of the team that conducted the trial, the ACTIV reviewers felt strongly that this agent should not be pursued in any ACTIV trial current or future for outpatients.

Please let us know if you have questions. Sarah and Eric were on the call with the reviewers and can attest to the definitive decision.

David and Cliff, please feel free to share this with Francis.

Cliff and Janet, this will not prevent our discussions about a trial for repurposed drugs with Gates and SIREN this week, but it may somewhat alleviate the extreme speed we thought would be needed. However, please let us know your thoughts.

Thanks,

b5

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: Mobile:

fnih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 1/21/2021 5:40:58 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Update on Ivermectin Discussion [b4]

Thanks, this is helpful. I let Josie know (in confidence) about the new development with ivermectin, but I agree it is still useful to pursue the more general model.

FC

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, January 21, 2021 11:53 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Update on Ivermectin Discussion [b4]

Francis:

I spoke with Stacey about this between ACTIV calls. The Columbian team did not do a subgroup analysis of their data. The team did note that the percentage of individuals over 50 was not enriched for, but between that population and other "at risk" populations with comorbidities, specifically obesity, the team felt they had a good cross-sampling.

We will need to go back to [b4] team to confirm start of therapy from symptom onset, but the window seemed similar to the other studies being conducted. The reviewers did note that the 12 day average time to symptom resolution in either IP or placebo suggests that these patients were indeed "sick," and that if an effect was going to be seen this should have been a sufficient amount of time in which to see it.

As with any trial [b4] study was not perfect, but their institution is experienced in and well respected for clinical trial conduct. They did switch the primary end point 1/3 of the way through the trial in the hope of better catching an effect if there was one, but the ACTIV team felt this was the right decision even if not typically great trial practice. The ACTIV team did not have any other criticisms about the conduct of the study, particularly given that it was conducted under pandemic conditions.

As for the conversation with PCORnet, I recall that while ivermectin was a catalyst for pursuing a pragmatic trial, the idea was to create a structure that would test multiple potential generic agents of public interest. The conversation between ACTIV and PCORnet on Tuesday was therefore broader than just ivermectin, so I would consider that nuance in your discussion with Josie if you decide to follow up with her.

David

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>

Sent: Thursday, January 21, 2021 6:45 AM

To: Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED]; Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 [REDACTED]; Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6 [REDACTED]; Freire, Maria (FNIH) [T] [REDACTED] b6 [REDACTED]; Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6 [REDACTED]; Anderson, James (NIH/OD) [E] [REDACTED] b6 [REDACTED]; Parker, Ashley (NIH/OD) [E] [REDACTED] b6 [REDACTED]; Patterson, Amy (NIH/NHLBI) [E] [REDACTED] b6 [REDACTED]; Adam, Stacey (FNIH) [T] [REDACTED] b6 [REDACTED]

Subject: RE: Update on Ivermectin Discussion [REDACTED] b4 [REDACTED]

+ Stacey

Thanks for sleuthing. This is very significant. Curious to know the time from symptom onset to start of therapy, and whether there were any subsets (older patients, patients with comorbidities) that showed a trend toward benefit? What will the ivermectin enthusiasts say was wrong with this trial?

I need to let Josie Briggs know about this, because she was looking into setting up an ivermectin trial through PCORnet.

FC

From: Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED]

Sent: Wednesday, January 20, 2021 10:31 PM

To: Collins, Francis (NIH/OD) [E] [REDACTED] b6 [REDACTED]; Tabak, Lawrence (NIH/OD) [E] [REDACTED] b6 [REDACTED]; Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6 [REDACTED]; Freire, Maria (FNIH) [T] [REDACTED] b6 [REDACTED]; Austin, Christopher (NIH/NCATS) [E] [REDACTED] b6 [REDACTED]; Anderson, James (NIH/OD) [E] [REDACTED] b6 [REDACTED]; Parker, Ashley (NIH/OD) [E] [REDACTED] b6 [REDACTED]; Patterson, Amy (NIH/NHLBI) [E] [REDACTED] b6 [REDACTED]

Subject: FW: Update on Ivermectin Discussion [REDACTED] b4 [REDACTED]

Just letting you (the war room crowd know). Cliff already copied on previous note.

From: Adam, Stacey (FNIH) [T] [REDACTED] b6 [REDACTED]

Sent: Wednesday, January 20, 2021 9:03 PM

To: Woodcock, Janet (FDA/CDER) [REDACTED] b6 [REDACTED]; Lane, Cliff (NIH/NIAID) [E] [REDACTED] b6 [REDACTED]; Wholley, David (FNIH) [T] [REDACTED] b6 [REDACTED]

Cc: Chen, Helen <qingchen@deloitte.com>; Appell, Evan <eappell@deloitte.com>; Read, Sarah (NIH/NIAID) [E] [REDACTED] b6 [REDACTED]; Eric Hughes <[REDACTED] b6 [REDACTED]>

Subject: Update on Ivermectin Discussion [REDACTED] b4 [REDACTED]

Dear Janet, Cliff and David,

I wanted to reach out to let you know that the conversation with [REDACTED] b4 [REDACTED] of ivermectin today. Provided what the ACTIV review panel for both immunomodulators and antivirals felt was compelling evidence for not pursuing a study with this agent. While the data is not published, it has been submitted to JAMA for review, and

is summarized below. With this information and the assessment of the team that conducted the trial, the ACTIV reviewers felt strongly that this agent should not be pursued in any ACTIV trial current or future for outpatients.

Please let us know if you have questions. Sarah and Eric were on the call with the reviewers and can attest to the definitive decision.

David and Cliff, please feel free to share this with Francis.

Cliff and Janet, this will not prevent our discussions about a trial for repurposed drugs with Gates and SIREN this week, but it may somewhat alleviate the extreme speed we thought would be needed. However, please let us know your thoughts.

Thanks,
Stacey

b5

b5

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Foundation for the National Institutes of Health

Direct: [b6] | Mobile: [b6]

fniih.org

11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 12/15/2020 8:00:18 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Happy Thanksgiving

Understand. Appreciate the follow-up. David

From: Wolinetz, Carrie (NIH/OD) [E] [b6]
Sent: Tuesday, December 15, 2020 2:55 PM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Happy Thanksgiving

Hi David,

Sigh.... Yes, I am aware. Not to put this too delicately, but this ball is in the court of the NIH Director, and he apparently requires another nudge.... I will sharpen my nudging stick... --C.

dam, Stacey (FNIH) [T] [b6]
Subject: RE: Happy Thanksgiving

Hi Carrie,
Mr. Cohen has apparently still heard nothing from NIH, as he pinged Stacey again on this issue yesterday morning. Can someone please reach out to him as soon as possible please?
Thanks,
David

From: Wholley, David (FNIH) [T]
Sent: Monday, December 7, 2020 1:55 PM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Happy Thanksgiving

Thank you, Carrie.

From: Wolinetz, Carrie (NIH/OD) [E] [b6]
Sent: Monday, December 7, 2020 1:53 PM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Happy Thanksgiving

Thanks, David – we can respond directly to Michael. Cheers, Carrie

Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health (NIH)

b6

<http://osp.od.nih.gov/>

Please follow on Twitter: @CWolinetzNIH



From: Wholley, David (FNIH) [T] b6
Sent: Monday, December 7, 2020 11:53 AM
To: Wolinetz, Carrie (NIH/OD) [E] b6 Parker, Ashley (NIH/OD) [E] b6
Cc: Freire, Maria (FNIH) [T] b6 Adam, Stacey (FNIH) [T] b6
Subject: FW: Happy Thanksgiving

Hi Carrie and Ashley:

As you know, CVS has been working with several NIH trials, including some ACTIV trials, on using their diagnostic and nursing services in order to provide referrals of COVID-19 positive patient or help with trial-related interventions. Shortly before Thanksgiving Michael Cohen reached out to FNIH via Stacey Adam to say that CVS has interest in providing these services, and perhaps others, more broadly to other NIH trials in other disease areas outside COVID. Via war room and other venues, I brought this request to Francis and Larry and asked how NIH wanted to handle it. Last I heard I thought there had been a discussion with the IC Directors and a conclusion reached to set up a call with interested ICs and CVS, but it appears from Michael's note below that no one from NIH has reached out. Rather than bother Francis or Larry directly I thought I would ask you what the status is, and whether you could respond directly to Michael's renewed request. Thanks, David

From: Adam, Stacey (FNIH) [T] b6
Sent: Monday, December 7, 2020 11:00 AM
To: Wholley, David (FNIH) [T] b6
Subject: FW: Happy Thanksgiving

FYI on CVS

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: b6 | Mobile: b6

From: Cohen, Michael J b6
Sent: Monday, December 7, 2020 9:40 AM
To: Adam, Stacey (FNIH) [T] b6
Subject: RE: Happy Thanksgiving

Hope you had a nice weekend. Just following up as no emails last week from those teams. Thank you for your help and championing CVS at NIH!

Best,
Michael

b6

Proprietary

From: Adam, Stacey (FNIH) [T] b6
Sent: Monday, November 30, 2020 12:32 PM
To: Cohen, Michael J b6
Subject: [EXTERNAL] RE: Happy Thanksgiving

**** External Email - Use Caution ****

Hi Michael,

Not that I know of, but I will keep you posted.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: b6 | Mobile: b6

From: Cohen, Michael J b6
Sent: Monday, November 30, 2020 12:29 PM
To: Adam, Stacey (FNIH) [T] b6
Subject: RE: Happy Thanksgiving

Thank you greatly appreciated! Do you need anything from me?

Talk soon!

Best,
Michael

b6

Proprietary

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To: Cohen, Michael J b6
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Hi Michael,

I hope you had a great Thanksgiving, as well!

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Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Cohen, Michael J [b6]
Sent: Monday, November 30, 2020 12:17 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Happy Thanksgiving

Hi Stacey,

Hope you had a Happy Thanksgiving!

Any updates from last week regarding Dr. Collins and how we can potentially work together outside of COVID?

Michael J Cohen (he/him/his)
Director, Pharmaceutical Commercialization
CVS Clinical Trial Services
m [b6]
e [b6]



Proprietary

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This e-mail may contain confidential or privileged information. If you think you have received this e-mail in error, please advise the sender by reply e-mail and then delete this e-mail immediately.

This e-mail may also contain protected health information (PHI) with information about sensitive medical conditions, including, but not limited to, treatment for substance use disorders, behavioral health, HIV/AIDS, or pregnancy. This type of information may be protected by various federal and/or state laws which prohibit any further disclosure without the express written consent of the person to whom it pertains or as otherwise permitted by law. Any unauthorized further disclosure may be considered a violation of federal and/or state law. A general authorization for the release of medical or other information may NOT be sufficient consent for release of this type of information. Thank you

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
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Sent: Monday, December 7, 2020 1:53 PM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
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Carrie D. Wolinetz, Ph.D.
Acting Chief of Staff and
Associate Director for Science Policy
Office of the Director
National Institutes of Health (NIH)

[b6]
<http://osp.od.nih.gov/>

Please follow on Twitter: @CWolinetzNIH



From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, December 7, 2020 11:53 AM

APAR0000001993

To: Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6]
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Sent: Monday, December 7, 2020 11:00 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: FW: Happy Thanksgiving

FYI on CVS

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Cohen, Michael J [b6]
Sent: Monday, December 7, 2020 9:40 AM
To: Adam, Stacey (FNIH) [T] [b6]
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Best,
Michael
347.963.8624

Proprietary

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Sent: Monday, November 30, 2020 12:32 PM
To: Cohen, Michael J [b6]
Subject: [EXTERNAL] RE: Happy Thanksgiving

**** External Email - Use Caution ****

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APAR0000001993

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Cohen, Michael J <Michael.Cohen@healthagen.com>

Sent: Monday, November 30, 2020 12:29 PM

To: Adam, Stacey (FNIH) [T] <sadam@fnih.org>

Subject: RE: Happy Thanksgiving

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[b6]

Proprietary

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Director, Cancer
Research Partnerships

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Michael J Cohen (he/him/his)

Director, Pharmaceutical Commercialization

CVS Clinical Trial Services

m [REDACTED] b6
e: [REDACTED] b6



Proprietary

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This e-mail may also contain protected health information (PHI) with information about sensitive medical conditions, including, but not limited to, treatment for substance use disorders, behavioral health, HIV/AIDS, or pregnancy. This type of information may be protected by various federal and/or state laws which prohibit any further disclosure without the express written consent of the person to whom it pertains or as otherwise permitted by law. Any unauthorized further disclosure may be considered a violation of federal and/or state law. A general authorization for the release of medical or other information may NOT be sufficient consent for release of this type of information. Thank you.

From: Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=60008133606B4F75835D3C77C2EEADB7-GILBERT.MAR]
Sent: 2/20/2021 2:50:55 PM
To: Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]
CC: Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Armstrong, Kimberly (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ba1621e98a14536995671b6a71caf1e-Kimberly.Ar]; King, Mason [b6]; Raahul, Ramakrishnan (bcg.com) [b6]. SES
USARMY DOD JPEO CBRND (USA) [b6]
Subject: Re: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Thanks Kevin

You'll see my note connecting you with Transcelerate. They will know contacts for ACRO and SCRS.

Best

Lynn

On Feb 20, 2021, at 8:36 AM, Bugin, Kevin [b6] wrote:

Good morning Tx Lessons Learned Leadership Group,
Thanks for your time yesterday for the kick-off of our leadership group for the therapeutics lessons learned initiative focused on clinical evaluation. Based on our discussion it sounds like we are aligned on:

- objectives, scope, approach for working group (WG), and emerging themes.
- WG additions: TransCelerate, ACRO, Society of Clinical Research Sites, patient groups (via Duke)
 - If folks have any personal contacts at TransCelerate, ACRO, or SCRS, please let me know!
- Duke-Margolis on board with lead on breakout WG, as is ACTIV but with a different facilitator (not Stacey)
- Need to keep an eye out for internal learnings and strategy, ensure these are tracked but remain separate from external working groups

As discussed, attached please the current version of the LL fact base that has emerged from the engagements with USG to date, particularly NIH/ACTIV.

Please let me know if you have any questions.

Kevin

-----Original Appointment-----

From: Woodcock, Janet <[b6]>

Sent: Wednesday, February 10, 2021 1:51 PM

To: Woodcock, Janet; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Adam, Stacey J (NIH); Armstrong, Kimberly (OS)

Cc: King, Mason; Ramakrishnan, Raahul; [b6] SES USARMY DOD JPEO CBRND (USA)
Subject: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off
When: Friday, February 19, 2021 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Webex

Purpose: Align on scope and approach for the USG COVID-19 Therapeutics Lessons Learned initiative.

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Join meeting

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APAR0000006401

From: Bugin, Kevin [b6]
Sent: 2/18/2021 10:35:19 PM
To: Woodcock, Janet (FDA/OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bc3fc3ebfcf48879f92169bd7644e29-Janet.Woodc]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60008133606b4f75835d3c77c2eeadb7-Gilbert.Mar]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Armstrong, Kimberly (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ba1621e98a14536995671b6a71caf1e-Kimberly.Ar]
CC: Victoria Davey [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c8291f38ec342f895243c0617e115ec-victoria.da]; [b6] CIV USARMY (USA)' [b6] SES USARMY DOD JPEO CBRND (USA)' [b6]
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off
Attachments: 20210216 Lessons Learned Initiative - Leadership Kick-off.vF.pptx

Good evening,

I hope all are well.

Attached please find materials to support our leadership group kick-off tomorrow. Many of you have seen some of this content already, but some of it is new. We will walk through all tomorrow.

Looking forward to the discussion. Thanks!

Kevin

-----Original Appointment-----

From: Woodcock, Janet [b6]
Sent: Wednesday, February 10, 2021 1:51 PM
To: Woodcock, Janet; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Adam, Stacey J (NIH); Armstrong, Kimberly (OS)
Cc: 'Davey, Victoria'; [b6] CIV USARMY (USA); [b6] SES USARMY DOD JPEO CBRND (USA)
Subject: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off
When: Friday, February 19, 2021 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Webex

Purpose: Align on scope and approach for the USG COVID-19 Therapeutics Lessons Learned initiative.

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From: McManus, Ayanna (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCF06DE08BA845249B9B36AD216E237E-AMCMANUS]
Sent: 5/15/2020 3:55:14 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Meeting with Moncef Slaoui on Monday

Got it, thanks!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 9:36 PM
To: McManus, Ayanna (NIH/OD) [E] [b6]
Subject: FW: Meeting with Moncef Slaoui on Monday

FYI – another participant John M.

From: Mascola, John (NIH/VRC) [E] [b6]
Sent: Thursday, May 14, 2020 9:08 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Meeting with Moncef Slaoui on Monday

Francis,

Happy to join the WebEx.

Thanks,
John

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 7:18 PM
To: Mascola, John (NIH/VRC) [E] [b6]; Erbeling, Emily (NIH/NIAID) [E] [b6]
Cc: Fauci, Anthony (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Meeting with Moncef Slaoui on Monday

Hi John and Emily,

Moncef Slaoui will be formally announced tomorrow as the head of the government's Operation Warp Speed. He's meeting this evening with Peter Marks and Janet Woodcock, and has accepted an invitation to meet virtually on Monday morning with the ACTIV "War Room" folks (including Larry Tabak, David Wholley, Cliff Lane, Chris Austin, Jim Anderson, Maria Freire, Ashley Parker, and me), Tony Fauci, Peter Marks, and Janet Woodcock. If there is any way that you could join that WebEx meeting, that would be terrific.

Just let me know if that might work for you.

Best, Francis

From: McManus, Ayanna (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BCF06DE08BA845249B9B36AD216E237E-AMCMANUS]
Sent: 5/15/2020 3:54:43 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Meeting with Moncef Slaoui on Monday

Thanks!

From: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Sent: Thursday, May 14, 2020 9:36 PM
To: McManus, Ayanna (NIH/OD) [E] <[REDACTED] b6 >
Subject: FW: Meeting with Moncef Slaoui on Monday

FYI – you are not on this thread.

From: Erbeling, Emily (NIH/NIAID) [E] <[REDACTED] b6 >
Sent: Thursday, May 14, 2020 9:08 PM
To: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >; Mascola, John (NIH/VRC) [E] <[REDACTED] b6 >
Cc: Fauci, Anthony (NIH/NIAID) [E] <[REDACTED] b6 >; Wholley, David (FNIH) [T] <[REDACTED] b6 >; Freire, Maria (FNIH) [T] <[REDACTED] b6 >; Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 >; Lane, Cliff (NIH/NIAID) [E] <[REDACTED] b6 >; Austin, Christopher (NIH/NCATS) [E] <[REDACTED] b6 >; Anderson, James (NIH/OD) [E] <[REDACTED] b6 >; Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Subject: RE: Meeting with Moncef Slaoui on Monday

I am happy to participate.
Thanks.
Emily

From: Collins, Francis (NIH/OD) [E] <[REDACTED] b6 >
Sent: Thursday, May 14, 2020 7:18 PM
To: Mascola, John (NIH/VRC) [E] <[REDACTED] b6 >; Erbeling, Emily (NIH/NIAID) [E] <[REDACTED] b6 >
Cc: Fauci, Anthony (NIH/NIAID) [E] <[REDACTED] b6 >; Wholley, David (FNIH) [T] <[REDACTED] b6 >; Freire, Maria (FNIH) [T] <[REDACTED] b6 >; Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 >; Lane, Cliff (NIH/NIAID) [E] <[REDACTED] b6 >; Austin, Christopher (NIH/NCATS) [E] <[REDACTED] b6 >; Anderson, James (NIH/OD) [E] <[REDACTED] b6 >; Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 >
Subject: Meeting with Moncef Slaoui on Monday

Hi John and Emily,

Moncef Slaoui will be formally announced tomorrow as the head of the government's Operation Warp Speed. He's meeting this evening with Peter Marks and Janet Woodcock, and has accepted an invitation to meet virtually on Monday morning with the ACTIV "War Room" folks (including Larry Tabak, David Wholley, Cliff Lane, Chris Austin, Jim Anderson, Maria Freire, Ashley Parker, and me), Tony Fauci, Peter Marks, and Janet Woodcock. If there is any way that you could join that WebEx meeting, that would be terrific.

Just let me know if that might work for you.

Best, Francis

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/6/2020 8:23:16 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Re: ACTIV Response Partnership Leadership Team Meeting #3

Ok – I sent him link and I believe he is on.
Thanks
larry

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, May 6, 2020 at 4:22 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6], "Melencio, Cheryl (FNIH) [T]" [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

Eliseo did not respond to the email to let Cheryl and David know he was available to attend – hence not receiving the calendar invite.

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 4:15 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Re: ACTIV Response Partnership Leadership Team Meeting #3

Eliseo Perez Stable, an ICD will be joining late. Apparently he never received the link.
Larry

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, May 6, 2020 at 3:33 PM
To: "Melencio, Cheryl (FNIH) [T]" [b6]
Cc: "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

I think this is OK – thank you for the update.

Ashley

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6] **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Wednesday, May 6, 2020 3:31 PM
To: Parker, Ashley (NIH/OD) [E]
Subject: FW: ACTIV Response Partnership Leadership Team Meeting #3
When: Wednesday, May 6, 2020 3:30 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us> [b6]

Dr. Burklow just forwarded the invite to Renate Myles

b6

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Meeting ID: **b6**

Password: **b6**

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From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/6/2020 7:34:19 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Re: ACTIV Response Partnership Leadership Team Meeting #3

It is fine

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Wednesday, May 6, 2020 at 3:33 PM
To: "Melencio, Cheryl (FNIH) [T]" [b6]
Cc: "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: RE: ACTIV Response Partnership Leadership Team Meeting #3

I think this is OK – thank you for the update.

Ashley

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6] **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Wednesday, May 6, 2020 3:31 PM
To: Parker, Ashley (NIH/OD) [E]
Subject: FW: ACTIV Response Partnership Leadership Team Meeting #3
When: Wednesday, May 6, 2020 3:30 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: <https://fnih.zoom.us> [b6]

Dr. Burklow just forwarded the invite to Renate Myles

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] **On Behalf Of** Wholley, David (FNIH) [T]
Sent: Friday, April 24, 2020 11:37 AM
To: Wholley, David (FNIH) [T]; Austin, Christopher (NIH/NCATS) [E]; Collins, Francis (NIH/OD) [E]; Corey, Larry; Disbrow, Gary (OS/ASPR/BARDA); Dolsten, Mikael; Erbelding, Emily (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]; Hudson, Thomas; James, Stephanie (FNIH) [T]; Johnson, Robert (OS/ASPR/BARDA); Kramer, Lynn; Lane, Cliff (NIH/NIAID) [E]; Marks, Peter (FDA/CBER); Marston, Hilary (NIH/NIAID) [E]; Mascola, John; Meeker, David; Menetski, Joseph (FNIH) [T]; Pangalos, Mene; Pao, William; Paul, Steve; Perlmutter, Roger; Plump, Andy; Rasi, Guido; Reed, John; Rouse, Doris; Santos, Michael (FNIH) [T]; Skovronsky, Daniel; Stein, Peter (FDA/CDER); Stoffels, Paul; Tabak, Lawrence (NIH/OD) [E]; Tsai, John; Vessey, Rupert; Virgin, Skip; Woodcock, Janet (FDA/CDER); Young, John; Colvis, Christine (NIH/NCATS) [E]; Desrosiers, Betsy; Hughes, Eric; Jansen, Kathrin; Kurilla, Michael (NIH/NCATS) [E]; Lowy, Douglas (NCI); Read, Sarah (NIH/NIAID) [E]; Freire, Maria (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Gonzalez, Nina; Kim, Elizabeth; Stratton, Ben; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Rachel Ramoni; Plenge, Robert; Talley, Michael; Cavaleri, Marco; Lee, William; Anderson, James (NIH/OD) [E]; Bianchi, Diana (NIH/NICHD) [E]; Brennan, Patti (NIH/NLM) [E]; Byrnes, Noni (NIH/CSR) [E]; Carter, Robert (NIH/NIAMS) [E]; Glass, Roger (NIH/FIC) [E]; Hodes, Richard (NIH/NIA) [E]; Koroshetz, Walter (NIH/NINDS) [E]; Norris, Andrea (NIH/CIT) [E]; Rodgers, Griffin (NIH/NIDDK) [E]; Schwetz, Tara (NIH/OD) [E]; Sharpless, Norman (NIH/NCI) [E]; Tucci, Debara (NIH/NIDCD) [E]; Tumminia, Santa (NIH/NEI) [E]; Volkow, Nora (NIH/NIDA) [E]; Wolinetz, Carrie (NIH/OD) [E]; Lankford, David (NIH/OD) [E]; Gibbons, Gary (NIH/NHLBI) [E]; Koob, George (NIH/NIAAA) [E]; Hallett, Adrienne (NIH/OD) [E]; Valantine, Hannah (NIH/OD) [E]; Gottesman, Michael (NIH/OD) [E]; Woychik, Rick (NIH/NIEHS) [E]; Cihlar, Tomas; Messonnier, Nancy

(CDC/DDID/NCIRD/OD); Langevin, Helene (NIH/NCCIH) [E]; Lauer, Michael (NIH/OD) [E]; Gallin, John (OD) [E]
Cc: Barasch, Kimberly (NIH/NIAID) [C]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Carver, Trea (NIH) [C]; Conrad, Patricia (NIH/NIAID) [E]; Hoffstetter, Renata (FNIH) [T]; Iberdemaj, Vaide; Lagos, Enrique (NIH/NCATS) [E]; McManus, Ayanna (NIH/OD) [E]; Melencio, Cheryl (FNIH) [T]; Protasiewicz, Ann; Simon, Dina (NIH/OD) [C]; Thomas, Ashley (FDA/CDER); Wood, Gretchen (NIH/OD) [E]; FNIH Central Account; Sepulveda, Dorina (FNIH) [T]; Li, Rose; Zottoli, Jessica; Lowy, Douglas (NIH/NCI) [E]; Parker, Ashley (NIH/OD) [E]; Gladman, Jordan (NIH/OD) [E]; Elsaid, Olivia; Best, Cindy (NIH/NEI) [E]; Bronson, Charlette (NIH/NIA) [E]; Dzokoto-Pomenya, Caroline (NIH/OD) [C]; Hamid, Khawar (NIH/CSR) [E]; Hardesty, Rebecca (NIH/OD) [C]; Hughes, Karen (NIH/OD) [E]; Kellton, Karen (NIH/OD) [C]; Mowery, Penny (NIH/NIDDK) [E]; New, Suzanne (NIH/NIDCR) [E]; Ott, Sandra (NIH/NICHD) [E]; Salley, Jasmine (NIH/NIDDK) [C]; Schulke, Hilda (NIH/NIDA) [E]; Shapiro-Loser, Beth (NIH/NIDDK) [E]; Stover, Kathleen (NIH/FIC) [E]; Togashi, Mieko (NIH/NCI) [E]; Wade, Portia (NIH/CIT) [E]; Barnett, Sylvia (NIH/OD) [E]; Dimishkov, Roxanne (NIH/NHLBI) [C]; Castillejos zenteno, Carlos [JRDUS]; Oresanya, Jejelola (NIH/OD) [C]; McBurney, Margaret (NIH/OD) [E]; Smith, Spencer (NIH/NIEHS) [E]; Denny, Joshua (NIH/OD) [E]; Council, Lisa (NIH/NCCIH) [C]; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]; Myles, Renate (NIH/OD) [E]

Subject: ACTIV Response Partnership Leadership Team Meeting #3

When: Wednesday, May 6, 2020 3:30 PM-5:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: <https://fnih.zoom.us/j/> **b6**

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US (San Jose)
US (Tacoma)

Meeting ID: **b6**

Password: **b6**

Find your local number: <https://fnih.zoom.us/j/> **b6**

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/6/2020 1:13:14 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

I have sent out notes disinviting deputy directors, and program office heads within the OD (yes, I love my job..). Members of FC's executive committee will join ICDs only. Thanks

Larry

From: "Wholley, David (FNIH) [T]" [b6]
Date: Wednesday, May 6, 2020 at 9:10 AM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6]
Cc: "Melencio, Cheryl (FNIH) [T]" [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Cheryl, can you please send Larry Tabak any notes requesting attendance at today's LT meeting received from NIHers since the list you sent out at about 6 PM last night? Please copy Ashley Parker on those notes. Thanks, David

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 8:36 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

This was the response I got from Joshua Denny.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]

fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Denny, Joshua (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 4:45 PM

APAR0000006729

To: Melencio, Cheryl (FNIH) [T] [b6] Wholley, David (FNIH) [T] [b6]
Cc: Schully, Sheri (NIH/OD) [E]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

David and Cheryl,

My apologies for the delayed response. Can Sheri still join for us? We (the All of Us Research Program) are also part of the vaccine population subgroup at this time.

thanks

Josh

On May 4, 2020, at 11:18 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Dear Colleagues,

As you may be aware, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership has been moving forward rapidly to address the global pandemic. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines.

Although some ICs have representatives participating in the working groups, we recognize there is a need to keep everyone looped in to the various activities and progress of the partnership, particularly in view of all of the concurrent IC projects about COVID-19. The ACTIV working groups will be delivering their second report to the **ACTIV Leadership Group on Wednesday, May 6, from 3:30-5:00pm**. I am writing to invite the ICDs to listen-in on this meeting. There will be a lot to cover during the meeting and the members of the Leadership Group will be asking the questions. But to give a chance for us NIHers to discuss what has been presented, I am scheduling a separate ICD call for 5:05-5:30pm, immediately following the ACTIV leadership meeting.

If you are available to take part, please send your responses to David Wholley and Cheryl Melencio of FNIH (cc'd here) by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and the ICD follow-up call.

Best regards,

Francis

From: Lauer, Michael (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=90FE9CAE30C64CFBB67ABD568E882796-LAUERM]
Sent: 5/6/2020 10:14:00 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fc28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Lauer, Michael (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=90fe9cae30c64cfbb67abd568e882796-lauerm]; Showe, Melanie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fbbbc74184e64f7e8a12d9faf8deb58f-showem]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Good morning – I would like to listen-in to the event running from 3:30 to 5:00 PM.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892

b6

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Monday, May 4, 2020 at 11:18 AM
To: "'icddir-l@list.nih.gov'" <ICDDIR-L@LIST.NIH.GOV>
Cc: "Parker, Ashley (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Melencio, Cheryl (FNIH) [T]" [b6]
Subject: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Dear Colleagues,

As you may be aware, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership has been moving forward rapidly to address the global pandemic. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines.

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If you are available to take part, please send your responses to David Wholley and Cheryl Melencio of FNIH (cc'd here) by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and the ICD follow-up call.

Best regards,
Francis

From: Valantine, Hannah (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A8B8263C5CC0442AAA0875846BD020E0-VALANTINEH]
Sent: 5/5/2020 6:52:58 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Oresanya, Jejelola (NIH/OD) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e6b58fd7ce540fba2283352ddf277e4-oresanyaj]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

I am available to take part in this meeting – please send me a calendar invite.
Many thanks
Hannah

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: Monday, May 4, 2020 at 08:18
To: "ICDDIR-L@LIST.NIH.GOV" <ICDDIR-L@LIST.NIH.GOV>
Cc: "Parker, Ashley (NIH/OD) [E]" [b6], "Wholley, David (FNIH) [T]" [b6], "Melencio, Cheryl (FNIH) [T]" [b6]
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Best regards,
Francis

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 5/5/2020 6:17:13 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Ok with me

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 12:00 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

From: Hallett, Adrienne (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 11:59 AM
Cc: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

I'd like to join to help formulate our Congressional outreach plans.

Thanks!
Adrienne Hallett
NIH Associate Director for Legislative Policy and Analysis

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Best regards,
Francis

From: Stakem, Maggi (NIH/CC/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=29B94D2D2A9C47878EDACBD114E49AF0-MSTAKEM]
Sent: 5/5/2020 5:10:21 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Stakem, Maggi (NIH/CC/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29b94d2d2a9c47878edacbd114e49af0-mstakem]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Unfortunately Dr. Gilman (NIH CC) has a conflict tomorrow afternoon and will not be able to join the ACTIV leadership meeting.

I hope you all are doing well ☺

Maggi

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 11:18 AM
To: ICDDIR-L@LIST.NIH.GOV
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6] Melencio, Cheryl (FNIH) [T] [b6]
Subject: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

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Best regards,
Francis

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E998E3770CFC7EE770-TABAKL]
Sent: 5/5/2020 5:06:09 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

thanks

From: "Wholley, David (FNIH) [T]" [b6]
Date: Tuesday, May 5, 2020 at 1:04 PM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6], Francis Collins [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

No concerns just wanted you to know she'll be on basically, since FC is talking to Senate HELP soon

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 12:08 PM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

David,
I am sure this will be fine. Adrienne is very discrete.
Please let me know if you have concerns.
Thanks,
Larry

From: "Wholley, David (FNIH) [T]" [b6]
Date: Tuesday, May 5, 2020 at 12:00 PM
To: Francis Collins [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: FW: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

From: Hallett, Adrienne (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 11:59 AM
Cc: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

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NIH Associate Director for Legislative Policy and Analysis

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Francis

From: Green, Eric (NIH/NHGRI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A25E392D22494E69916325297A9212D7-EGREEN]
Sent: 5/5/2020 12:47:31 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

I can participate in the 5:05 pm ICD follow-up call (not the earlier meeting).
Please send the relevant link.

Thanks,

Eric

Eric Green, M.D., Ph.D.

Director, National Human Genome Research Institute
National Institutes of Health
31 Center Dr., Bldg. 31, Rm. 4B09
Bethesda, MD 20892-2152

b6

[@NHGRI Director](http://www.genome.gov/about-NHGRI/Director)



National Human Genome
Research Institute

The **Forefront**
of **Genomics**

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 11:18 AM
To: ICDDIR-L@LIST.NIH.GOV
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
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Best regards,
Francis

From: Bronson, Charlette (NIH/NIA) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=048D4C0B49984BABAAEDD3448DED4AB4-BRONSONC]
Sent: 5/4/2020 3:54:40 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Hodes, Richard (NIH/NIA) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaaf8902643342969c60fd551f81a159-hodesr]
Subject: Re: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Hi Cheryl,

Dr. Hodes will join both meetings on Wednesday, May 6.

Sent from my iPhone

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Best regards,
Francis

From: Simon, Dina (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E02345FA5D1D4D7EAF4E0F3DA58BC1AC-SIMONDM]
Sent: 5/4/2020 3:28:09 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: Re: DRAFT EMAIL TO SEND | ICD Invite to ACTIV Leadership Meeting 5/6

Thank you, Ashley

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Monday, May 4, 2020 at 10:11 AM
To: "Simon, Dina (NIH/OD) [C]" [b6]
Cc: "Melencio, Cheryl (FNIH) [T]" [b6]
Subject: RE: DRAFT EMAIL TO SEND | ICD Invite to ACTIV Leadership Meeting 5/6

Hi Dina,

FYI for Dr. Tabak's calendar – additional meeting on Wed. 5/6, 5:05-5:30pm – cc'ing Cheryl who will be handling the calendar invites.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, May 4, 2020 10:08 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Melencio, Cheryl (FNIH) [T] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]
Subject: DRAFT EMAIL TO SEND | ICD Invite to ACTIV Leadership Meeting 5/6

Hi Francis,

Please see draft email to the ICDs inviting them to attend the ACTIV leadership meeting, 5/6. I spoke with Cheryl and she is anticipating receiving their responses and will send the calendar invites for both the ACTIV leadership meeting and follow-up call.

Thanks,
Ashley

DRAFT EMAIL TO ICDs:

Dear Colleagues,

As you may be aware, the ACTIV public private partnership has been moving at warp speed and although some ICs have put forth representatives to participate in the working groups, we recognize there is a need to keep everyone looped in to the various activities and progress of the partnership. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical capacity, and vaccines.

On April 22nd, the working group co-chairs, one from industry and NIH reported their initial progress and shared timelines with the ACTIV leadership group.

In addition to ACTIV, many of the ICs are developing and progressing COVID-19 projects and we want to ensure we are well coordinated. This seems to be an opportune time invite NIH leadership to join the ACTIV leadership meetings which are currently happening twice per month.

We will have our next readout to the **ACTIV leadership group on Wednesday, May 6, 3:30-5:00pm**, I am writing to invite the ICDs to listen-in on this meeting. We have lots to cover during the meeting and understand there may be questions for us to discuss internally. In addition, we are scheduling a separate ICD call, 5:05-5:30pm with the ACTIV working group co-chairs and FNIH immediately after the ACTIV leadership meeting.

If you are available to attend, please send your responses to FNIH, David Wholley and Cheryl Melencio by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and ICD follow-up call.

Sincerely,
Francis

From: Stover, Kathleen (NIH/FIC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7A372032E1B4999B57BC64B2E59304B-STOVERKA]
Sent: 5/4/2020 3:23:47 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Invitation to join (virtually) the ACTIV Leadership Meeting 5/6

Good morning,

Thank you for inviting Dr. Roger Glass to join the ACTIV leadership meeting and the ICD follow-up call. Dr. Glass is very interested in participating in both on Wednesday.

Thank you and best,

Kitty

Kitty Stover

Assistant to the Director
Fogarty International Center
NIH Associate Director for International Research
National Institutes of Health
31 Center Drive, Room B2C02
Bethesda, MD 20892-2220

P: [REDACTED] b6
F: 301.402.2173

From: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Sent: Monday, May 4, 2020 11:18 AM
To: ICDDIR-L@LIST.NIH.GOV
Cc: Parker, Ashley (NIH/OD) [E] [REDACTED] b6 Wholley, David (FNIH) [T] [REDACTED] b6 Melencio, Cheryl (FNIH) [T] [REDACTED] b6
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Dear Colleagues,

As you may be aware, the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) public-private partnership has been moving forward rapidly to address the global pandemic. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines.

Although some ICs have representatives participating in the working groups, we recognize there is a need to keep everyone looped in to the various activities and progress of the partnership, particularly in view of all of the concurrent IC projects about COVID-19. The ACTIV working groups will be delivering their second report to the **ACTIV Leadership Group on Wednesday, May 6, from 3:30-5:00pm**. I am writing to invite the ICDs to listen-in on this meeting. There will be a lot to cover during the meeting and the members of the Leadership Group will be asking the questions. But to give a chance for us NIHers to discuss what has been presented, I am scheduling a separate ICD call for 5:05-5:30pm, immediately following the ACTIV leadership meeting.

If you are available to take part, please send your responses to David Wholley and Cheryl Melencio of FNIH (cc'd here) by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and the ICD follow-up call.

Best regards,
Francis

From: Simon, Dina (NIH/OD) [C] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E02345FA5D1D4D7EAF4E0F3DA58BC1AC-SIMONDM]
Sent: 5/4/2020 2:23:49 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: DRAFT EMAIL TO SEND | ICD Invite to ACTIV Leadership Meeting 5/6

Thank you

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Monday, May 4, 2020 at 10:11 AM
To: "Simon, Dina (NIH/OD) [C]" [b6]
Cc: "Melencio, Cheryl (FNIH) [T]" [b6]
Subject: RE: DRAFT EMAIL TO SEND | ICD Invite to ACTIV Leadership Meeting 5/6

Hi Dina,

FYI for Dr. Tabak's calendar – additional meeting on Wed. 5/6, 5:05-5:30pm – cc'ing Cheryl who will be handling the calendar invites.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, May 4, 2020 10:08 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Melencio, Cheryl (FNIH) [T] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]
Subject: DRAFT EMAIL TO SEND | ICD Invite to ACTIV Leadership Meeting 5/6

Hi Francis,

Please see draft email to the ICDs inviting them to attend the ACTIV leadership meeting, 5/6. I spoke with Cheryl and she is anticipating receiving their responses and will send the calendar invites for both the ACTIV leadership meeting and follow-up call.

Thanks,
Ashley

DRAFT EMAIL TO ICDs:

Dear Colleagues,

As you may be aware, the ACTIV public private partnership has been moving at warp speed and although some ICs have put forth representatives to participate in the working groups, we recognize there is a need to keep everyone looped in to the various activities and progress of the partnership. We held our initial ACTIV leadership meeting on April 3rd including, NIH, FDA, BARDA, EMA, and industry heads of research and development. Four working groups were formed out of this meeting to focus on preclinical therapeutics, clinical therapeutics, clinical capacity, and vaccines.

On April 22nd, the working group co-chairs, one from industry and NIH reported their initial progress and shared timelines with the ACTIV leadership group.

In addition to ACTIV, many of the ICs are developing and progressing COVID-19 projects and we want to ensure we are well coordinated. This seems to be an opportune time invite NIH leadership to join the ACTIV leadership meetings which are currently happening twice per month.

We will have our next readout to the **ACTIV leadership group on Wednesday, May 6, 3:30-5:00pm**, I am writing to invite the ICDs to listen-in on this meeting. We have lots to cover during the meeting and understand there may be questions for us to discuss internally. In addition, we are scheduling a separate ICD call, 5:05-5:30pm with the ACTIV working group co-chairs and FNIH immediately after the ACTIV leadership meeting.

If you are available to attend, please send your responses to FNIH, David Wholley and Cheryl Melencio by noon tomorrow, May 5th. Once you confirm your attendance, Cheryl will send you a calendar invite for both the ACTIV leadership meeting and ICD follow-up call.

Sincerely,
Francis

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/4/2020 2:49:09 AM
To: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

Modification – please also include Walter Koroshetz and members of his leadership team as well.

Thanks

Larry

From: "Tabak, Lawrence (NIH/OD) [E]" [b6]
Date: Saturday, May 2, 2020 at 11:17 AM
To: "McManus, Ayanna (NIH/OD) [E]" [b6], "Wood, Gretchen (NIH/OD) [E]" [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

As you will read, Francis wants to meet with Gary and his leadership team about ACTIV early next week. Please include everyone in the "To" line below; Gary will need to decide who to invite but I imagine that will include him, Amy Paterson, and Steve Goff at a minimum.

Thanks

Larry

From: Francis Collins [b6]
Date: Saturday, May 2, 2020 at 10:57 AM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

I think I need to be involved for this one.

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Saturday, May 2, 2020 9:48 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

Francis,

Can Chris and David Wholley handle this for you? or do you need to be involved?

Larry

From: Francis Collins [b6]
Date: Saturday, May 2, 2020 at 9:13 AM
To: "Tabak, Lawrence (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6]

[REDACTED], "Wholley, David (FNIH) [T]" [REDACTED], "Adam, Stacey (FNIH) [T]"
[REDACTED], "Tountas, Karen (FNIH) [T]" [REDACTED] "Austin, Christopher (NIH/NCATS) [E]"
[REDACTED]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

Sorry that wasn't clear. Need to start with NHLBI. Gary agreed to that.

From: Tabak, Lawrence (NIH/OD) [E] [REDACTED]
Sent: Saturday, May 2, 2020 9:03 AM
To: Collins, Francis (NIH/OD) [E] [REDACTED]; Parker, Ashley (NIH/OD) [E] [REDACTED]; Wholley, David (FNIH) [T] [REDACTED]; Adam, Stacey (FNIH) [T] [REDACTED]; Tountas, Karen (FNIH) [T] [REDACTED]; Austin, Christopher (NIH/NCATS) [E] [REDACTED]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

To be clear, do you want a special ICDs meeting to review ACTIV with all of them, or a meeting with senior NHLBI staff?
Thanks
Larry

From: Francis Collins [REDACTED]
Date: Saturday, May 2, 2020 at 8:27 AM
To: "Tabak, Lawrence (NIH/OD) [E]" [REDACTED]; "Parker, Ashley (NIH/OD) [E]" [REDACTED]; "Wholley, David (FNIH) [T]" [REDACTED]; "Adam, Stacey (FNIH) [T]" [REDACTED]; "Tountas, Karen (FNIH) [T]" [REDACTED]; "Austin, Christopher (NIH/NCATS) [E]" [REDACTED]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

Hi all, (somehow this was stuck in my outbox from yesterday afternoon)

I spoke with Gary Gibbons just now. I'm glad we connected because there is a fairly serious issue here. The NHLBI ROA on host-targeted therapies for COVID-19 was planned before ACTIV came into being. Gary and colleagues thought it was their responsibility to act quickly to harness the clinical trial capacity of PETAL and other networks that they support. That was of course a highly appropriate response to the crisis, and that's how they got their HCQ trial started.

It's clear, however, that Gary is not very well informed about ACTIV. He says David Goff has been giving him occasional updates, but David is very stretched by other duties. I told Gary he is welcome to add another representative so that could be better informed about the Clinical Therapeutics and Clinical Trials Capacity Working Groups.

He says the ROA has created a buzz in his clinical community, who are largely unaware of ACTIV. I tried to fill him in on where we are with the candidate therapeutic prioritization, the master protocol, and the capacity survey. He said that the PIs of NHLBI's networks might not take kindly to a master protocol that they hadn't had input to. I pushed back that this is not the time for academic squabbles that consume months, but a bit of command and control will be needed. He acknowledged that and said he had been preparing the ground for that to happen.

He was clearly suggesting that IC Directors should be better informed about ACTIV. In his case, that's definitely true.

I suggested there should be a meeting early next week where he and his senior staff involved in clinical trials could go over all of these issues and get fully briefed by relevant ACTIV co-chairs about the status of these efforts and the timetables involved.

Can we work on setting that up?

Francis

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 11:44 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

On it

From: Francis Collins <[b6]>
Date: Thursday, April 30, 2020 at 11:43 AM
To: "Parker, Ashley (NIH/OD) [E]" [b6]; "Tabak, Lawrence (NIH/OD) [E]" [b6]; "Wholley, David (FNIH) [T]" [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

So this is puzzling. Yes, Larry, please reach out to Gary.

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 11:16 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

Yes, we have him listed on the clinical capacity WG.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 11:11 AM
To: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: COVID19-ROA-OTA-FINAL.pdf

First I am seeing also. Isn't David Goff of NHLBI on ACTIV?

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 10:46 AM
To: Wholley, David (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: COVID19-ROA-OTA-FINAL.pdf

First I am seeing this. Francis, do you want me to reach out to Gary?

From: "Wholley, David (FNIH) [T]" [b6]
Date: Thursday, April 30, 2020 at 10:34 AM
To: Francis Collins [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6]
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

Francis and Larry:

Perhaps I am misunderstanding the intent of this announcement but it seems more than a little duplicative of what we are trying to do in ACTIV. My co-chairs certainly seem to think so. Can someone offer a perspective we can communicate on this please? Thanks, David

From: "Read, Sarah (NIH/NIAID) [E]" [b6]
Date: April 29, 2020 at 10:45:05 PM EDT
To: "Adam, Stacey (FNIH) [T]" [b6] Eric Hughes [b6]
Subject: FW: COVID19-ROA-OTA-FINAL.pdf

This is interesting. I can't figure out the date of when this was published but it reads like a funding announcement for ACTIV...minus antivirals.

<https://www.nhlbi.nih.gov/sites/default/files/media/docs/COVID19-ROA-OTA-FINAL.pdf>

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 10/2/2020 12:39:41 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: ACTIV Cross Trial meetings

Thanks, Ashley! You too!

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, October 2, 2020 8:33 AM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: ACTIV Cross Trial meetings

Thanks, Stacey and happy Friday if that means anything! 😊

Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, October 2, 2020 8:31 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV Cross Trial meetings

Hi Ashley,

The larger Cross Trial ACTIV meetings are only the 4th Friday of every month, so none today, but I will get you on them.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, October 2, 2020 8:29 AM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: ACTIV Cross Trial meetings

Hi Stacey,

Sorry, can I get the invite for any ACTIV cross trial meetings today (Fridays) if appropriate?

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, September 30, 2020 8:32 AM
To: Adam, Stacey (FNIH) [T] <[b6]>
Subject: RE: ACTIV Cross Trial meetings

Thanks, Stacey!

From: Adam, Stacey (FNIH) [T] <[b6]>
Sent: Wednesday, September 30, 2020 8:29 AM
To: Parker, Ashley (NIH/OD) [E] <[b6]>
Subject: RE: ACTIV Cross Trial meetings

Hi Ashley,

Sure thing.

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

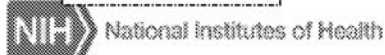
From: Parker, Ashley (NIH/OD) [E] <[b6]>
Sent: Wednesday, September 30, 2020 8:25 AM
To: Adam, Stacey (FNIH) [T] <[b6]>
Subject: ACTIV Cross Trial meetings

Hi Stacey,

Could your team please send me the calendar invitations for the ACTIV Cross Trial meetings? I know there are some conflicts on my calendar for Thursdays meeting but I would like to join these whenever I can.

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



From: Hawk, Harrison [hhawk@deloitte.com]
Sent: 10/21/2020 9:19:05 PM
To: [b6] Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory [b6] Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Reynolds, Lindsey [b6]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]
Subject: RE: ACTIV Preclinical - Data Portal Implementation
Attachments: 20201015_ACTIV Preclinical_Data Portal Implementation Notes_vF.docx

Hi All,

Please see attached for the meeting notes from our meeting on 10/15. Apologies for the delay in sending these, and let us know if you suggest any edits.

Best,
Harrison

Harrison Hawk
Deloitte Consulting LLP
Mobile: [b6]
www.deloitte.com

-----Original Appointment-----

From: Hawk, Harrison
Sent: Wednesday, October 14, 2020 9:38 AM
To: Hawk, Harrison; [b6] Hewitt, Judith (NIH/NIAID) [E]; [b6] Gatto, Gregory; Young, John; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; Stratton, Benjamin; [b6] Rodriguez, Robin D; Jonson, Samantha (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Hild, Sheri (NIH/OD) [E]; Reynolds, Lindsey; Florence, Clint (NIH/NIAID) [E]; Mason, Stephen; Connelly, Sarah
Subject: ACTIV Preclinical - Data Portal Implementation
When: Thursday, October 15, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).
Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

Hi all,

APAR0000022480

We've updated the cadence for the Data Portal Implementation meeting to be once monthly. We will also be establishing reminders to provide updates for the animal model data portal offline. Be on the lookout for those invites as well.

Thanks!

Harrison



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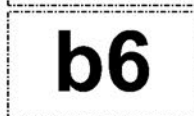


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From: Connelly, Sarah [sconnelly@deloitte.com]
Sent: 10/14/2020 9:54:18 PM
To: [b6] Hewitt, Judith (NIH/NIAID) [E]
 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] Gatto, Gregory [b6] Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Stratton, Benjamin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed7188]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Rodriguez, Robin D [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Reynolds, Lindsey [b6]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6]
CC: Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]
Subject: RE: ACTIV Preclinical - Data Portal Implementation

Hi All,

Below please find the agenda for tomorrow's data portal implementation meeting. Please reach out with any questions or concerns.

Agenda Topic	Duration	Facilitator
New animal model webpage updates	10 mins	Samantha Jonson
Discuss new additions to page (including the viral reference strain recommendation criteria, mouse model literature)	20 mins	Samantha Jonson
Animal model social media communication templates update	10 mins	Samantha Jonson Ashley Parker
Updates on the NHP study-level data portal	10 mins	Jay Rappaport

Looking forward to our discussion!

Best,
 Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: +1 571 882 8808
www.deloitte.com

-----Original Appointment-----

From: Hawk, Harrison <hhawk@deloitte.com>

Sent: Wednesday, October 14, 2020 8:38 AM

To: Hawk, Harrison; [b6]; Hewitt, Judith (NIH/NIAID) [E]; [b6]; Gatto, Gregory; Young, John; Colvis, Christine (NIH/NCATS) [E]; Menetski, Joseph (FNIH) [T]; Ottinger, Elizabeth (NIH/NCATS) [E]; Stratton, Benjamin; [b6] Rodriguez, Robin D; Jonson, Samantha (NIH/NCATS) [E]; Parker, Ashley (NIH/OD) [E]; Hild, Sheri (NIH/OD) [E]; Reynolds, Lindsey; Florence, Clint (NIH/NIAID) [E]; Mason, Stephen; Connelly, Sarah

Subject: ACTIV Preclinical - Data Portal Implementation

When: Thursday, October 15, 2020 9:00 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])

Hi all,

We've updated the cadence for the Data Portal Implementation meeting to be once monthly. We will also be establishing reminders to provide updates for the animal model data portal offline. Be on the lookout for those invites as well.

Thanks!

Harrison



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b6

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b6

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after you have joined the meeting. If you continue to participate in the meeting following these warnings, your participation will serve as your express consent to such recording.

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From: Connelly, Sarah [sconnelly@deloitte.com]
Sent: 10/9/2020 6:30:47 PM
To: Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; [b6] [b6] Gatto, Gregory [b6]; Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]; [b6] Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6] [b6] Tomas Cihlar [b6] [b6] CIV USARMY MEDCOM USAMRIID (USA) [b6] Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Prabhavathi Fernandes [b6] Diamond, Michael [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; [b6] Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6] Baric, Toni C [b6]; Rodriguez, Robin D [b6] Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Connelly, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user3ed93bab]
Subject: RE: ACTIV Preclinical Working Group Meeting - Scenario Planning Discussion
Attachments: ACTIV_Preclinical WG_Planning Excercise_Proposal Template_10092020_v1.docx; ACTIV_Preclinical WG_Planning Excercise_Themes_100820_v1.pptx

Dear Preclinical Working Group Members,

For those of you who didn't attend our meeting this morning, we discussed the major strategic objectives that came out of the scenario planning exercise. Please see the attached slides for more context as well as the high-level list of strategic objectives below.

As a next step, we are asking for volunteers to form small working groups (approx. 2-3 people per group) to build out proposals for each of these strategic objectives. A template of the proposal format is attached for context. Please reply to email **by Monday October 12th**, to express interest in joining one or more of the 5 groups below.

Top strategic objectives from the planning exercise:

1. **Continue to harmonize and validate models, protocols and assays:** Continue our efforts to centralize up-to-date preclinical protocols and best practices to ensure robust data sets across sites and studies to standardize results and facilitate data comparison
2. **Distill key findings to advance knowledge:** Consolidation, organization and dissemination of preclinical findings in a connected or centralized manner to keep the field up to date on major advancements in the field
3. **Coordinate preclinical and clinical data and insights:** Enable better coordination between clinical study data and findings with animal model development and validation, particularly to address late stages of disease, comorbidities and long-haulers
4. **Develop a portfolio strategy for prioritization:** Focus on a strategic portfolio of agents that identify gaps in stages of therapy (e.g. oral antivirals to treat early infections, broad spectrum RNA antiviral for future pandemics, etc.) to address high unmet need areas
5. **Create a robust preparedness plan for the future:** Support preparedness for future pandemics by developing a playbook that consolidates lessons learned, assesses gaps in capabilities, and provides resources to target future pandemics

Please reach out if you have any questions.

Regards,
Sarah

Sarah Connelly, PhD
Deloitte Consulting, LLP
Tel/Direct: +1 571 882 8808
www.deloitte.com

-----Original Appointment-----

From: Alvarez, Rosa Maria <rosalvarez@deloitte.com>

Sent: Monday, October 5, 2020 10:12 AM

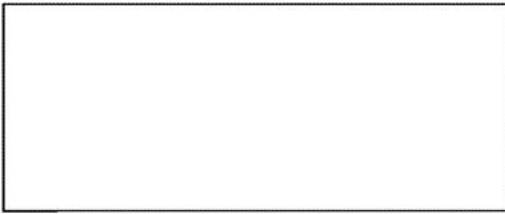
To: Alvarez, Rosa Maria; [REDACTED] Menetski, Joseph (FNIH) [T]; Young, John; Colvis, Christine (NIH/NCATS) [E]; [REDACTED] Nancy Haigwood; Hild, Sheri (NIH/OD) [E];

[REDACTED]; Gatto, Gregory; Baric, Ralph; [REDACTED]
Ottinger, Elizabeth (NIH/NCATS [E]; Hewitt, Judith (NIH/NIAID) [E]; [REDACTED]
Parker, Ashley (NIH/OD) [E]; [REDACTED] Tomas Cihlar; [REDACTED]
CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; [REDACTED] Fessel, Josh
(NIH/NHLBI) [E]; Prabhavathi Fernandes; Diamond, Michael; Jonson, Samantha (NIH/NCATS) [E]; [REDACTED]
Florence, Clint (NIH/NIAID) [E]; Mason, Stephen; Baric, Toni C; Rodriguez, Robin D; [REDACTED] Hawk,
Harrison; Connelly, Sarah

Subject: ACTIV Preclinical Working Group Meeting - Scenario Planning Discussion

When: Friday, October 9, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [https://deloitte.zoom.us/j/\[REDACTED\]](https://deloitte.zoom.us/j/[REDACTED])



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From: Connelly, Sarah [sconnelly@deloitte.com]
Sent: 11/5/2020 11:10:24 PM
To: Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6]
 [b6] CIV USARMY MEDCOM USAMRIID (USA)
 [b6] Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Rodriguez, Robin D [b6]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Gatto, Gregory [b6]; Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; Young, John [b6]; Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]
CC: Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: RE: ACTIV Preclinical - In Vivo Strategy

Hi All,

Please see below for the agenda for tomorrow's meeting at 10:00 AM ET. If you have any questions or items to add, please let us know.

Agenda Topic	Duration	Facilitator
Discuss the possibility of developing additional small animal model presentations	20 mins	Joe Menetski John Young Christine Colvis
Updates on Small animal model field guide development	10 mins	Isis Kanovsky Cat Lutz
Updates on offline NHP field guide work	10 mins	Nancy Haigwood Jay Rappaport
Updates on BEI viral stock production (as needed)	10 mins	Clint Florence
Align on action items and next steps	10 mins	Joe Menetski Sarah Connelly

Looking forward to talking to everyone tomorrow!

All the best,
 Sarah

Sarah Connelly, PhD
 Deloitte Consulting, LLP

APAR0000022509

-----Original Appointment-----

From: Hawk, Harrison <hhawk@deloitte.com>

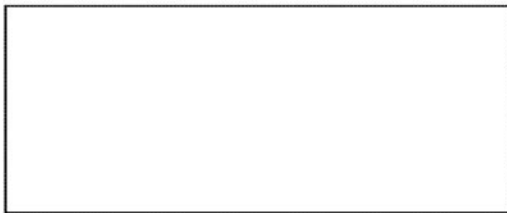
Sent: Friday, October 16, 2020 1:07 PM

To: Hawk, Harrison; Alvarez, Rosa Maria; [b6] Menetski, Joseph (FNIH) [T]; Colvis, Christine (NIH/NCATS) [E]; [b6] CIV USARMY MEDCOM USAMRIID (USA); [b6] Hild, Sheri (NIH/OD) [E]; Florence, Clint (NIH/NIAID) [E]; Rodriguez, Robin D; [b6] Parker, Ashley (NIH/OD) [E]; Ottinger, Elizabeth (NIH/NCATS) [E]; Gatto, Gregory; Jonson, Samantha (NIH/NCATS) [E]; Connelly, Sarah; Young, John; Nancy Haigwood

Subject: ACTIV Preclinical - In Vivo Strategy

When: Friday, November 6, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [https://deloitte.zoom.us/\[b6\]](https://deloitte.zoom.us/[b6])



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From: Connelly, Sarah [sconnelly@deloitte.com]
Sent: 10/9/2020 1:52:39 PM
To: Alvarez, Rosa Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user706e5647]; Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Young, John [b6] Colvis, Christine (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b7e84cce098457896b2df19fa172c87-ccolvis]; [b6] Nancy Haigwood [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03d589f440d84691ac0a530e4ba6ceb5-haigwoon.oh]; Hild, Sheri (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=edd7f1939fb94be3bf063f925ac15f02-hildsa]; [b6]; Gatto, Gregory [b6] Ottinger, Elizabeth (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad34123055944f97bedbef038d375cd7-ottingerea]; Hewitt, Judith (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d0a7dadfcbd42cbb4014d9b26af30cc-jhewitt]; [b6] [b6] Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; [b6] Tomas Cihlar [b6] [b6] IV USARMY MEDCOM USAMRIID (USA) [b6] Punturieri, Antonello (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca7f3106e5f24b5cb5e933c6ee7a6bc7-punturiera]; Charette, Marc (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7fa2baf951848b5bf1f76a049a0eca6-charettemf]; Fessel, Josh (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=294e2bb481d94b83a1917f15338dfe19-fesseljp]; Prabhavathi Fernandes [b6]; Diamond, Michael [b6] Jonson, Samantha (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce2f69369d654bef89b0d39b145d69a7-jonsonsg]; [b6] Florence, Clint (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e032d0bc8554e8787e844a7773295fe-florencewc]; Mason, Stephen [b6] Baric, Toni C [b6] Rodriguez, Robin D [b6] Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Hawk, Harrison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user280c84f8]; [b6] Baric, Ralph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e35ab1d3044465a7790ee4ded5bc32-rbaric.email]
Subject: RE: ACTIV Preclinical Working Group Meeting - Scenario Planning Discussion
Attachments: ACTIV_Preclinical WG_Planning Excercise_Themes_100820_v1.pptx

Hi All,

Attached are the materials that we will use to guide our working group meeting this morning. We look forward to the discussion.

Thanks,
Sarah

Sarah Connelly, PhD
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Tel/Direct: +1 571 882 8808
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APAR0000022513

-----Original Appointment-----

From: Alvarez, Rosa Maria <rosalvarez@deloitte.com>

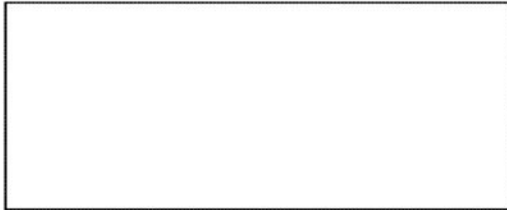
Sent: Monday, October 5, 2020 10:12 AM

To: Alvarez, Rosa Maria; [b6] Menetski, Joseph (FNIH) [T]; Young, John; Colvis, Christine (NIH/NCATS) [E]; [b6] Nancy Haigwood; Hild, Sheri (NIH/OD) [E]; [b6]; Gatto, Gregory; [b6] Ottinger, Elizabeth (NIH/NCATS) [E]; Hewitt, Judith (NIH/NIAID) [E]; [b6] Parker, Ashley (NIH/OD) [E]; [b6]; Tomas Cihlar; [b6] CIV USARMY MEDCOM USAMRIID (USA); Punturieri, Antonello (NIH/NHLBI) [E]; [b6] Fessel, Josh (NIH/NHLBI) [E]; Prabhavathi Fernandes; Diamond, Michael; Jonson, Samantha (NIH/NCATS) [E]; [b6] Florence, Clint (NIH/NIAID) [E]; Mason, Stephen; Baric, Toni C; Rodriguez, Robin D; [b6] Hawk, Harrison; Connelly, Sarah; [b6] Baric, Ralph

Subject: ACTIV Preclinical Working Group Meeting - Scenario Planning Discussion

When: Friday, October 9, 2020 10:00 AM-11:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: [https://deloitte.zoom.us/j/\[b6\]](https://deloitte.zoom.us/j/[b6])



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From: Lohmann, Larry (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93F4206CBB2C4D82ADBC1EDA15E035C4-LOHMANNLL]
Sent: 9/29/2020 12:31:22 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Berkson, Laura (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=adb561ab47e54fdc94e2a54682514434-berksonld]
Subject: Re: COVID-19 preclinical research - ACTIV

Ashley,

I think it is a good response. I will run it through ASL and get back to the committee. If there is any additional follow-ups, I will let you know.

Very respectfully,
Larry

Larry Lohmann, Esq.

Office of Legislative Policy & Analysis
National Institutes of Health

[REDACTED] b6 C/telework

From: "Parker, Ashley (NIH/OD) [E]" [REDACTED] b6
Date: Monday, September 28, 2020 at 12:07 PM
To: "Lohmann, Larry (NIH/OD) [E]" [REDACTED] b6, "Berkson, Laura (NIH/OD) [E]" [REDACTED] b6
Subject: Re: COVID-19 preclinical research - ACTIV

Hi Larry and Laura,

Is the response below sufficient for what you need to pull for the E&C Minority staff?

Thanks,
Ashley

From: Menetski, Joseph (FNIH) [T] [REDACTED] b6
Sent: Monday, September 28, 2020 11:44 AM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6; Colvis, Christine (NIH/NCATS) [E] [REDACTED] b6
Cc: Anderson, James (NIH/OD) [E] [REDACTED] b6; Lohmann, Larry (NIH/OD) [E] [REDACTED] b6
Berkson, Laura (NIH/OD) [E] [REDACTED] b6
Subject: RE: COVID-19 preclinical research - ACTIV

Dear Ashley,

Does this cover your questions and needs? Please let us know if there is anything else we can do.

Currently, ACTIV does not have funding to support research. With regard to animal models, the role that ACTIV has taken is to provide information and guidance to the research with regard to which models are appropriate for which types of studies. We also have a portal through which researchers may submit their agent (generally small molecule, but biologics have been submitted) information for consideration for testing in one of the ACTIV clinical trials. For agents that look promising, but need additional animal studies, the submitter is notified and asked if they have the ability to conduct the studies or need assistance. Thus far, most cases have been able to use small animals, which are not limited in supply, although there may be some limitations in ABSL3 space. If they need assistance, we connect them to the NIAID staff who manage contracts for such studies. If they have the financial resources to pay for studies, we connect them to one of the sites that has fee for service capabilities and capacity. So far we have guided 6 assets through the initial stages of match making, 2 assets came from public sources (NIH and academic PIs) while 6 were associated with small biotech companies. Overall there are an additional 15 assets that are in line to go through the match-making process, 4 of those are from public sources (NIH and academic PIs) and 11 are from industry sponsors (small and large biotech). Access to facilities where funding is available (generally through NIAID) is very limited (2-3 facilities) and the backup in testing is substantial (1-2 compounds per month, over 10 compounds are waiting). We are trying to guide sponsors to other contract organizations, but not all sponsors have the ability to support the preclinical studies needed.

Since ACTIV does not have funding to support research, projects that need NHPs are directed to submit their proposal (regardless of funding source) to <https://redcap.ncats.nih.gov/redcap/surveys/?s=TLX93TDDMR>. In general before any NHPs will be used, small animal studies would be conducted first to avoid unnecessary use of the NHPs. Thus far, the primary focus for NHPs has been on vaccine development, which is primarily being directed by OWS. That said, ACTIV has not seen requests for NHP studies from OWS. Because of the limited number of NHPs and the lack of a validated model for inflammatory response to SARS-CoV2 in these animals, we have only suggested 1 asset for NHP testing. We have also been encouraging validation studies with NHPs to model the inflammatory sequelae induced by SARS-CoV2, particularly in the African Green Monkey. ACTIV has played a key role in ensuring that the NHP studies conducted at the NPRCs are harmonized to allow sharing of control animals across different studies (which will reduce the total number of animals needed) and that they are aligned with the ACTIV master protocols to make it easier to compare between human trials and NHP studies.

Best regards,
Joe (and Christine)

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, September 24, 2020 11:25 AM
To: Colvis, Christine (NIH/NCATS) [E] [b6] >
Cc: Anderson, James (NIH/OD) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6];
Lohmann, Larry (NIH/OD) [E] [b6]; Berkson, Laura (NIH/OD) [E] [b6]
Subject: Re: COVID-19 preclinical research - ACTIV

Hi Christine,

I received the note below asking me to coordinate the response to the follow up questions from the briefing you had with the House Minority Committee on Tuesday regarding the ACTIV preclinical WG.

We can provide the committee with a link to the ACTIV website for the preclinical WG roster however OLPA needs responses to the remaining questions.

Could we please have responses to these questions by Monday, 9/28? Cc'ing Jim and Joe per the note below.

1. Rosters of the preclinical working group and the committee prioritizing requests (Committee will treat as non-public close holds); <https://www.nih.gov/research-training/medical-research-initiatives/activ/preclinical-working-group#members>

2. The number of companies that ACTIV has assisted with ABSL-3 lab space requests;
3. The number of companies that ACTIV has assisted with animal model requests; and
4. Which supply of animals is so limited that going overseas is necessary.

Thanks,
Ashley

From: Lohmann, Larry (NIH/OD) [E] { b6 }
Sent: Thursday, September 24, 2020 10:41 AM
To: Parker, Ashley (NIH/OD) [E] { b6 }; Berkson, Laura (NIH/OD) [E] { b6 }
Subject: Re: COVID-19 preclinical research - ACTIV

Good morning Ashley,

Dr. Anderson recommended Christine Colvis w/NCATS for this briefing that was held on 9/22. Dr. Colvis did a fantastic job, but there were a few follow-up questions that still need to be answered for E&C Minority staff. Dr. Colvis believed most of the unanswered questions could be answered by Jim Anderson or Joe Menetski. Could you please help me round up the information for the items below so I can respond to the committee?

Very respectfully,
Larry Lohmann

Larry Lohmann, Esq.

Office of Legislative Policy & Analysis
National Institutes of Health

{ b6 } C/telework

Rosters of the preclinical working group and the committee prioritizing requests (Committee will treat as non-public close holds);
The number of companies that ACTIV has assisted with ABSL-3 lab space requests;
The number of companies that ACTIV has assisted with animal model requests; and
Which supply of animals is so limited that going overseas is necessary.

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/4/2020 10:22:36 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: Re: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Thanks, Ashley,
Coming shortly.
Stacey

Sent from my iPhone. Please excuse the brevity and typos.

On Nov 4, 2020, at 5:20 PM, Parker, Ashley (NIH/OD) [E] <[b6]> wrote:

Sorry, catching up on emails. I will standby for the revised versions.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 5:19 PM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E]
[b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Thanks, David,

I will also change that too.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 5:17 PM
To: Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

The slide titles should also make it clear for Francis which is for presentation and which just for private reference. I don't think the current titles accomplish that.

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 4:21 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Ashley,

My apologies we just caught an slight error in both slide sets. Please use these but the descriptions below still apply.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Adam, Stacey (FNIH) [T]
Sent: Wednesday, November 4, 2020 4:09 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Ashley,

My apologies. I have slides I just have not had a chance to send them to you yet.

Please see attached two versions. One version is a simplified summary that FC can use to present. The second version is the full summary of agents and where they ranked. This second one cannot be presented in a public forum, but we wanted FC to have it in case he gets questions.

David, do you think this is an acceptable solution to your early concern about making the compounds reviewed public?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, November 4, 2020 3:07 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Stacey,

Just checking to see if we are on schedule to receive the ACTIV antiviral summary slide today. Francis has requested that I send the complete package by COB today.

Thanks,
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, November 2, 2020 11:35 AM
To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E]
[b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi David,

You raise good point. We have made it a policy not to show which agents we have reviewed and where we have placed them to the public, as it could have market effects. I had for a moment forgotten this Summit would be public. We had shared the details with Hever. I will work with Evan to get something at the right level for summary.

As for the Merck drug, I just sent you another email as requested.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, November 2, 2020 10:19 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Stacey, the question also is whether this is something Francis can show the Summit attendees. If not, we need to signal that and describe what he can show. In addition, Francis asked this morning if we know anything about what is going on with the Merck/Ridgeback drug and whether Merck is/would consider bringing it into any of the ACTIV protocols. You can send me that under separate cover when you get the chance. Thanks, David

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, November 2, 2020 8:27 AM
To: Wholley, David (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6]
Subject: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Good morning David and Stacey,

David, per the conversation on the war room call this morning – attached is the slide Francis would like to have updated for his presentation for the NIH Antiviral Tx Summit on Friday, 11/6.

Looping in Stacey as requested. Francis has requested an updated draft by Wed, 11/4 – hopefully this works for the FNIH team.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the Chief of Staff and NIH Director for Accelerating COVID-19
Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [REDACTED] b6
<image001.png>

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 11/4/2020 10:18:08 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi David,

Okay, we can do that I was not sure if FC would want to at least talk about those we are moving forward. I will remove those and put class on the one to be presented.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 5:15 PM
To: Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Wait, is it OK to mention the specifics on Sagent, Merck, and Synairgen? I thought we were only going to mention drug MOA or class?

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 4:09 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi Ashley,

My apologies. I have slides I just have not had a chance to send them to you yet.

Please see attached two versions. One version is a simplified summary that FC can use to present. The second version is the full summary of agents and where they ranked. This second one cannot be presented in a public forum, but we wanted FC to have it in case he gets questions.

David, do you think this is an acceptable solution to your early concern about making the compounds reviewed public?

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Stacey

Stacey J. Adam, PhD

Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

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Sent: Wednesday, November 4, 2020 3:07 PM
To: Adam, Stacey (FNIH) [T] [b6]
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Hi Stacey,

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Thanks,
Ashley

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Sent: Monday, November 2, 2020 11:35 AM
To: Wholley, David (FNIH) [T] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Hi David,

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As for the Merck drug, I just sent you another email as requested.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, November 2, 2020 10:19 AM
To: Parker, Ashley (NIH/OD) [E] [b6] Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Stacey, the question also is whether this is something Francis can show the Summit attendees. If not, we need to signal that and describe what he can show. In addition, Francis asked this morning if we know anything about what is going on with the Merck/Ridgeback drug and whether Merck is/would consider bringing it into any of the ACTIV protocols. You can send me that under separate cover when you get the chance. Thanks, David

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, November 2, 2020 8:27 AM

To: Wholley, David (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6]

Subject: Updated Slide for NIH Antiviral Therapeutics Summit 11/6

Good morning David and Stacey,

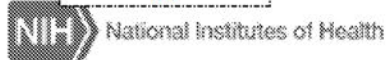
David, per the conversation on the war room call this morning – attached is the slide Francis would like to have updated for his presentation for the NIH Antiviral Tx Summit on Friday, 11/6.

Looping in Stacey as requested. Francis has requested an updated draft by Wed, 11/4 – hopefully this works for the FNIH team.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the Chief of Staff and NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health

Tel: [b6]



From: Kolberg, Rebecca (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=30071513C5A8433A98883FD78D360A91-KOLBERGR]
Sent: 11/6/2020 11:06:33 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Pelis, Kim (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d27af8a8b53f4728a25e9b83984ce9f1-pelisk]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: FC Slides
Attachments: SARS CoV-2 Antiviral Meeting_110620_v4 jpm.pptx

Hi Renate,

Per your request, I'm forwarding what I think is the final version of FC's seminar slides (which FC said looked fine in response to Joe's email). Jill worked with Ashley Parker on these. So, if Ashley has anything to add please, weigh in!

Rebecca

From: "Menetski, Joseph (FNIH) [T]" [b6]
Date: Wednesday, November 4, 2020 at 9:06:51 PM
To: "Collins, Francis (NIH/OD) [E]" [b6] "Adam, Stacey (FNIH) [T]" [b6]
"Parker, Ashley (NIH/OD) [E]" [b6]
Cc: "George, Jill (NIH/OD) [E]" [b6] "Pelis, Kim (NIH/OD) [E]" [b6]
"Kolberg, Rebecca (NIH/OD) [E]" [b6] "Wolinetz, Carrie (NIH/OD) [E]" [b6]
[b6], "Wholley, David (FNIH) [T]" [b6]
Subject: RE: Speeches Update 23

Dear Francis,

You are correct, we made an initial decision of which team would review based on the reported stage of development. However, 5 of the agent sponsors reported a higher level of COVID-19 development than was actually the case and the agent was re-reviewed by the preclinical team.

I have updated the footnote to be more explicit. It now says: "5 antiviral candidates were reviewed first by the clinical team, reclassified as preclinical and then reviewed by the preclinical team"

If this needs more detail, we can generate another slide to show the process, but I think that could go too far in the weeds. However, happy to put something together if you think it would add to the talk.

Let us know if this helps.

Joe

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, November 4, 2020 8:28 PM
To: Adam, Stacey (FNIH) [T] [b6] Parker, Ashley (NIH/OD) [E] [b6]

Cc: George, Jill (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6] Kolberg, Rebecca (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6] Menetski, Joseph (FNIH) [T] [b6] Wholley, David (FNIH) [T] [b6]
Subject: RE: Speeches Update 23

Sorry, I was looking for something a bit more clarifying about exactly how the two groups are defining the boundaries here. I assume a therapeutic in the preclinical prioritization group has never been in human trials. Right? And a clinical therapeutic has been at least through Phase 1. So how can there be five compounds that are in both categories?

Francis

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 8:13 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6] Menetski, Joseph (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Speeches Update 23

Hi Francis,

I have updated the titles of slides 6 and 7 to reflect which is preclinical and clinical. Do you need us to better describe the overlap or is this okay?

In addition, I have updated slide 8 to reflect all currently public information that can be shared.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, November 4, 2020 8:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6] Pelis, Kim (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6] Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6] Wholley, David (FNIH) [T] [b6]
Subject: RE: Speeches Update 23

OK, except there needs to be an explicit statement on slides 6 and 7 about the distinction between these two prioritized lists. What's preclinical and what's clinical (especially if there's an overlap of 5)? Can that be added? Looping in Stacey and Joe.

FC

From: Parker, Ashley (NIH/OD) [E] | [REDACTED] b6
Sent: Wednesday, November 4, 2020 6:03 PM
To: Collins, Francis (NIH/OD) [E] | [REDACTED] b6
Cc: George, Jill (NIH/OD) [E] | [REDACTED] b6 ; Pelis, Kim (NIH/OD) [E] | [REDACTED] b6 ; Kolberg, Rebecca (NIH/OD) [E] | [REDACTED] b6 ; Wolinetz, Carrie (NIH/OD) [E] | [REDACTED] b6
Subject: RE: Speeches Update 23

Hi Francis,

Please see the attached slides for the Antiviral Summit, 11/6. FNIH provided slides 6-7 for the ACTIV antiviral prioritization summary and as you can see the decision was made not to show the names of the compounds publicly. For your reference, Stacey has included a version of these two slides with the names of the compounds and I've placed them in the back packet (slides 11-12).

Please let us know once you clear and we will transmit the final version to Jim Anderson.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, November 2, 2020 1:08 AM
To: Collins, Francis (NIH/OD) [E] | [REDACTED] b6
Cc: George, Jill (NIH/OD) [E] | [REDACTED] b6
Subject: Re: Speeches Update 23

Thanks, Francis. Need attachment for the 11/6 Antiviral Tx Summit.

I will follow up with FNIH on Wednesday and circle back with you the same day as indicated below.

Thanks,
Ashley

On Nov 1, 2020, at 4:23 PM, Collins, Francis (NIH/OD) [E] | [REDACTED] b6 wrote:

Hi all,

Thanks for staying on top of all of these upcoming events – seems like a pretty busy time!

See comments/responses below in **BOLD CAPS**.

Francis

From: George, Jill (NIH/OD) [E] | [REDACTED] b6
Sent: Friday, October 30, 2020 5:06 PM
To: Collins, Francis (NIH/OD) [E] | [REDACTED] b6
Cc: Pelis, Kim (NIH/OD) [E] | [REDACTED] b6 ; Kolberg, Rebecca (NIH/OD) [E] | [REDACTED] b6 ; Burklow, John (NIH/OD) [E] | [REDACTED] b6 ; Myles, Renate (NIH/OD) [E] | [REDACTED] b6 ; Akinso, Woleola (NIH/OD) [E] | [REDACTED] b6 ; Wolinetz, Carrie (NIH/OD) [E] | [REDACTED] b6 ; Parker, Ashley (NIH/OD) [E] | [REDACTED] b6 ; Wood, Gretchen (NIH/OD) [E] | [REDACTED] b6 ; McManus, Ayanna (NIH/OD) [E]

Subject: Speeches Update 23

<image002.jpg>Hi Francis,

Happy Halloween!

Here's you Friday update.

11/2-3 Progeria Research Foundation's 10th International Scientific Workshop

1. Livestreaming, via Zoom, 10am-1pm, Monday & Tuesday
2. Organizers were contacted and are not expecting a pre-recorded backup
 1. You are both a presenter and a moderator on Tuesday
 2. Presentation is livestreaming, 12 min, followed by 5 min Q&A
3. Given your email exchange with Dr. Gordon, we did not attend the dry run. **Would you like us to relay any questions to the organizers? NO, I THINK I'M ALL SET, I JUST NEED TO FINALIZE THE PRESENTATION, BUT THAT'S ON ME.**

11/5 2020 NIH Distinguished Scholars Program—meeting with NIH leadership

4. Livestreaming, via Zoom, 11am-noon
5. Provide 15 min of remarks and participate in Q&A (moderated by Carl Hashimoto)
 1. Personal career and leadership story
 2. Tips for success as PI at NIH and generally
6. Speeches will provide agenda and information on Scholars **OK, I WILL WATCH FOR THAT**

11/6 NIH Virtual SARS-CoV-2 Antiviral Therapeutics Summit

7. Livestreaming, via a proprietary webcast platform from BAV Services, 11am-4pm
8. You will be providing brief introductory remarks and a longer closing statement (Draft slides from Jill/Ashley and suggested talking points from Matt Hall/Jim Anderson are attached)
9. Slides will be placed in a centrally compiled deck and are needed on or before **Nov 5**
 1. **Please confirm which of the two Antivirals Prioritization Summary slides, 7 or 8, we should develop. I'VE DONE A LITTLE EDITING – SEE ATTACHED FILE. PLEASE CHECK WITH FNIH ON WEDNESDAY ABOUT THE ACCURACY OF SLIDE 6, IN CASE THAT NEEDS UPDATING. AND THEN PLEASE REMIND ME WEDNESDAY COB TO HAVE ONE MORE LOOK, IN CASE THERE'S A NEED FOR LAST MINUTE TWEAKING.**

11/6 Video for the Hereditary Disease Foundation's Gala, 11/17

1. Prerecording, via Zoom, 10-10:30am
2. Provide 8-10 min keynote on how, despite the global pandemic, HD and related research continues; introduce the Inaugural Nancy Wexler Investigator's Prize
3. Draft run of show attached
4. Speeches has requested talking points from HDF and NIH research updates from NINDS
5. Speeches will provide agenda and formatted Talking Points. **Do you need anything else? I DON'T THINK SO. PROBABLY THEY WILL EXPECT SOME PERSONAL REFLECTIONS ON THE COLLABORATIVE EFFORT, SUPPORTED BY HDF, THAT IDENTIFIED THE HD GENE BACK IN 1993.**

11/12 Conversation with Rev. Rick Warren

10. Livestreaming, via Zoom, 45 min. Details are still being worked out with Rick Warren's office
11. A conversation-style interview, similar to the 10/7 faith leaders event with Dr. Birx, for wide circulation in evangelical circles
12. Discussion to include the holidays and the importance of compliance with public health measures, and updates on COVID-19 treatments and vaccine research

13. Speeches will provide a run-of-show and Rev. Warren's bio. **Are you set? I THINK SO. I KNOW REV. WARREN PRETTY WELL, THIS SHOULD BE A COMFORTABLE DISCUSSION. SEND ME THE RUN OF SHOW WHEN YOU GET IT.**

11/12 Ignatius Forum: What's Next with COVID

14. Livestreaming from the Cathedral, 7-8:30pm
15. We will know more after receiving the logistics form (sent out just to the organizers this afternoon), but **do you have any specific requests for speeches at this time? NOT AT THE MOMENT, JUST NEED TO UNDERSTAND THE FORMAT A BIT BETTER.**

11/19 Brookings Board of Trustees meeting on COVID-19 crisis and current state of the pandemic

16. Livestreaming, via Zoom, 2:55-3:45pm. They have provided this agenda:
1. Dr. Collins joins the Zoom meeting
2. 3:00pm Dr. Wen introduces Dr. Collins and begins a fireside chat. (Dr. Collins is welcome to make 3-5 minutes of prepared remarks at the top if he would like.)
3. 3:20pm Dr. Wen opens the conversation to audience questions
4. 3:45pm Dr. Wen thanks Dr. Collins and concludes
17. They asked that NIH provide a contact to discuss your topics/questions in advance with Dr. Wen. **Whom do you want to serve as that contact? ASHLEY PARKER.**

Based on this Update, we do **NOT** think a Speeches meeting will be needed next week.

FC Response: ☒ Agree ☐ Disagree ☐ Maybe, if time allows

Thanks,
Your Speeches Team

FYI Only—Talks scheduled through December 2020

- 11/10 American Society for Microbiology (Not yet formally accepted)
11/16 Enhancers, Gene Regulation and Genome Organization meeting
11/16 AAMC Opening Plenary, COVID-19: Where Do We Go from Here?
11/18 Health Journalism Summit on Infectious Diseases
11/18 WALSH: Emery Brown, M.D., Ph.D., Rethinking General Anesthesia
11/19 Brookings Board of Trustees meeting on COVID-19 crisis and current state of the pandemic
11/20 NIH Town Hall
12/1 2020 NIH Behavioral and Social Sciences Research Festival
12/15 ORWH's 30th Anniversary Scientific Symposium

Jill George
NIH Office of the Director/OCPL

b6 Skype
Cell

NIH ... *Turning Discovery Into Health®*

From: Collins, Francis (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=410E1CA313F44CED9938E50D2FF0B6C2-COLLINSF]
Sent: 11/5/2020 9:46:13 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Speeches Update 23

Yes, please send to Jim

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, November 5, 2020 1:09 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: Speeches Update 23

Should I send the attached slides minus the back pocket to Jim or you've taken care of it?

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, November 5, 2020 6:00 AM
To: Menetski, Joseph (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Speeches Update 23

That should take care of it, thanks!
FC

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 9:05 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Speeches Update 23

Dear Francis,

You are correct, we made an initial decision of which team would review based on the reported stage of development. However, 5 of the agent sponsors reported a higher level of COVID-19 development than was actually the case and the agent was re-reviewed by the preclinical team.

I have updated the footnote to be more explicit. It now says: "5 antiviral candidates were reviewed first by the clinical team, reclassified as preclinical and then reviewed by the preclinical team"

If this needs more detail, we can generate another slide to show the process, but I think that could go too far in the weeds. However, happy to put something together if you think it would add to the talk.

Let us know if this helps.

Joe

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, November 4, 2020 8:28 PM
To: Adam, Stacey (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Speeches Update 23

Sorry, I was looking for something a bit more clarifying about exactly how the two groups are defining the boundaries here. I assume a therapeutic in the preclinical prioritization group has never been in human trials. Right? And a clinical therapeutic has been at least through Phase 1. So how can there be five compounds that are in both categories?

Francis

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, November 4, 2020 8:13 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Speeches Update 23

Hi Francis,

I have updated the titles of slides 6 and 7 to reflect which is preclinical and clinical. Do you need us to better describe the overlap or is this okay?

In addition, I have updated slide 8 to reflect all currently public information that can be shared.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, November 4, 2020 8:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Adam, Stacey (FNIH)

[T] [b6]; Menetski, Joseph (FNIH) [T] [b6] Wholley, David (FNIH) [T]
[b6]

Subject: RE: Speeches Update 23

OK, except there needs to be an explicit statement on slides 6 and 7 about the distinction between these two prioritized lists. What's preclinical and what's clinical (especially if there's an overlap of 5)? Can that be added? Looping in Stacey and Joe.

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, November 4, 2020 6:03 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Pelis, Kim (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6] Wolinetz, Carrie (NIH/OD) [E] [b6]
Subject: RE: Speeches Update 23

Hi Francis,

Please see the attached slides for the Antiviral Summit, 11/6. FNIH provided slides 6-7 for the ACTIV antiviral prioritization summary and as you can see the decision was made not to show the names of the compounds publicly. For your reference, Stacey has included a version of these two slides with the names of the compounds and I've placed them in the back packet (slides 11-12).

Please let us know once you clear and we will transmit the final version to Jim Anderson.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, November 2, 2020 1:08 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: Re: Speeches Update 23

Thanks, Francis. Need attachment for the 11/6 Antiviral Tx Summit.

I will follow up with FNIH on Wednesday and circle back with you the same day as indicated below.

Thanks,
Ashley

On Nov 1, 2020, at 4:23 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi all,

Thanks for staying on top of all of these upcoming events – seems like a pretty busy time!

See comments/responses below in **BOLD CAPS**.

Francis

From: George, Jill (NIH/OD) [E] [b6]
Sent: Friday, October 30, 2020 5:06 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Pelis, Kim (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Akinso, Woleola (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]
Subject: Speeches Update 23

<image002.jpg>Hi Francis,

Happy Halloween!

Here's your Friday update.

11/2-3 Progeria Research Foundation's 10th International Scientific Workshop

- Livestreaming, via Zoom, 10am-1pm, Monday & Tuesday
- Organizers were contacted and are not expecting a pre-recorded backup
 - You are both a presenter and a moderator on Tuesday
 - Presentation is livestreaming, 12 min, followed by 5 min Q&A
- Given your email exchange with Dr. Gordon, we did not attend the dry run. **Would you like us to relay any questions to the organizers? NO, I THINK I'M ALL SET, I JUST NEED TO FINALIZE THE PRESENTATION, BUT THAT'S ON ME.**

11/5 2020 NIH Distinguished Scholars Program—meeting with NIH leadership

- Livestreaming, via Zoom, 11am-noon
- Provide 15 min of remarks and participate in Q&A (moderated by Carl Hashimoto)
 - Personal career and leadership story
 - Tips for success as PI at NIH and generally
- Speeches will provide agenda and information on Scholars **OK, I WILL WATCH FOR THAT**

11/6 NIH Virtual SARS-CoV-2 Antiviral Therapeutics Summit

- Livestreaming, via a proprietary webcast platform from BAV Services, 11am-4pm
- You will be providing brief introductory remarks and a longer closing statement (Draft slides from Jill/Ashley and suggested talking points from Matt Hall/Jim Anderson are attached)
- Slides will be placed in a centrally compiled deck and are needed on or before **Nov 5**
 - **Please confirm which of the two Antivirals Prioritization Summary slides, 7 or 8, we should develop. I'VE DONE A LITTLE EDITING – SEE ATTACHED FILE. PLEASE CHECK WITH FNIH ON WEDNESDAY ABOUT THE ACCURACY OF SLIDE 6, IN CASE THAT NEEDS UPDATING. AND THEN PLEASE REMIND ME WEDNESDAY COB TO HAVE ONE MORE LOOK, IN CASE THERE'S A NEED FOR LAST MINUTE TWEAKING.**

11/6 Video for the Hereditary Disease Foundation's Gala, 11/17

- Prerecording, via Zoom, 10-10:30am
- Provide 8-10 min keynote on how, despite the global pandemic, HD and related research continues; introduce the Inaugural Nancy Wexler Investigator's Prize
- Draft run of show attached
- Speeches has requested talking points from HDF and NIH research updates from NINDS

- Speeches will provide agenda and formatted Talking Points. **Do you need anything else? I DON'T THINK SO. PROBABLY THEY WILL EXPECT SOME PERSONAL REFLECTIONS ON THE COLLABORATIVE EFFORT, SUPPORTED BY HDF, THAT IDENTIFIED THE HD GENE BACK IN 1993.**

11/12 Conversation with Rev. Rick Warren

- Livestreaming, via Zoom, 45 min. Details are still being worked out with Rick Warren's office
- A conversation-style interview, similar to the 10/7 faith leaders event with Dr. Birx, for wide circulation in evangelical circles
- Discussion to include the holidays and the importance of compliance with public health measures, and updates on COVID-19 treatments and vaccine research
- Speeches will provide a run-of-show and Rev. Warren's bio. **Are you set? I THINK SO. I KNOW REV. WARREN PRETTY WELL, THIS SHOULD BE A COMFORTABLE DISCUSSION. SEND ME THE RUN OF SHOW WHEN YOU GET IT.**

11/12 Ignatius Forum: What's Next with COVID

- Livestreaming from the Cathedral, 7-8:30pm
- We will know more after receiving the logistics form (sent out just to the organizers this afternoon), but **do you have any specific requests for speeches at this time? NOT AT THE MOMENT, JUST NEED TO UNDERSTAND THE FORMAT A BIT BETTER.**

11/19 Brookings Board of Trustees meeting on COVID-19 crisis and current state of the pandemic

- Livestreaming, via Zoom, 2:55-3:45pm. They have provided this agenda:
 - Dr. Collins joins the Zoom meeting
 - 3:00pm Dr. Wen introduces Dr. Collins and begins a fireside chat. (Dr. Collins is welcome to make 3-5 minutes of prepared remarks at the top if he would like.)
 - 3:20pm Dr. Wen opens the conversation to audience questions
 - 3:45pm Dr. Wen thanks Dr. Collins and concludes
- They asked that NIH provide a contact to discuss your topics/questions in advance with Dr. Wen. **Whom do you want to serve as that contact? ASHLEY PARKER.**

Based on this Update, we do **NOT** think a Speeches meeting will be needed next week.

FC Response: ☒ Agree ☐ Disagree ☐ Maybe, if time allows

Thanks,
Your Speeches Team

FYI Only—Talks scheduled through December 2020

- 11/10 American Society for Microbiology (Not yet formally accepted)
- 11/16 Enhancers, Gene Regulation and Genome Organization meeting
- 11/16 AAMC Opening Plenary, COVID-19: Where Do We Go from Here?
- 11/18 Health Journalism Summit on Infectious Diseases
- 11/18 WALSH: Emery Brown, M.D., Ph.D., Rethinking General Anesthesia
- 11/19 Brookings Board of Trustees meeting on COVID-19 crisis and current state of the pandemic
- 11/20 NIH Town Hall
- 12/1 2020 NIH Behavioral and Social Sciences Research Festival
- 12/15 ORWH's 30th Anniversary Scientific Symposium

Jill George
NIH Office of the Director/OCPL

b6

NIH ... Turning Discovery Into Health®

From: Wohl, David A [b6]
Sent: 11/3/2020 7:58:59 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: Contact for UNC Site for ACTIV-2

Hi

My cell is [b6]

Feel free to call.

D

From: Adam, Stacey (FNIH) [T] [b6]
Date: Tuesday, November 3, 2020 at 2:58 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wohl, David A [b6]
Subject: Contact for UNC Site for ACTIV-2

Hi Ashley,

ACTIV-2 is open and enrolling at UNC. Dr. David Wohl, the site PI there, has asked if you can call him to discuss. His number is [b6]. I have also cc'd him on this email if that is easier.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Foundation for the National Institutes of Health
Direct: [b6] Mobile: [b6]
fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



From: Wolinetz, Carrie (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1C655040D47346C7B04D7BC11A403ECB-WOLINETZCD]
Sent: 9/4/2020 1:03:25 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
CC: Berger, Adam (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cfbf537ab62640ffa150a8f65241879f-bergerac]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Koniges, Ursula (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d5ae2c3139654bc0b9b95718d516310b-konigesum]
Subject: RE: FW: Discussion about Short Site Survey to Determine COVID Trial Burden

Thanks, I can close the (absurd) loop on this during our check in.

From: Culp, Michelle (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 3:46 PM
To: Wolinetz, Carrie (NIH/OD) [E] [b6]
Cc: Berger, Adam (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6] Koniges, Ursula (NIH/OD) [E] [b6]
Subject: FYI: FW: Discussion about Short Site Survey to Determine COVID Trial Burden

Dear Carrie,

I'm just returning from a couple days of leave and being unplugged. In catching up, I saw these notes on ideas for ACTIV 2 & 3 recruitment solutions, and mention of the **central IRB letter**.

Item #10 in the attached notes from David Wholley (section pasted below) mentions the central IRB letter as a good model. The notes made me wonder if the IRB letter was distributed, and if not, is FNIH and study teams are aware of the final messaging in the IRB letter.

10. A few additional notes/caveats on such a public campaign: It should ideally have a global component, since COVID-19 is a global pandemic and a good number of our sites are outside the U.S. Although we might be able to use the ACTIV protocols as an example of the kind of studies in which people should participate (as opposed to small, underpowered studies that are the norm), we need to be very careful that this is a general exhortation to participate in COVID-19 trials, and not appear to be exclusionary, or we will hear vocal objections to say the least from other trial sponsors. Also, the central IRB letter authored by Francis Collins and a related letter sent to the study PIs offers a good model. Finally, any such communication needs both a general public component (a PSA) and a targeted, study-specific component, as evidenced by the public engagement strategy followed with convalescent plasma.

-Michelle

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, August 28, 2020 8:16 PM
To: Adam, Stacey (FNIH) [T] [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6]; McNay, Laura (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Bugin, Kevin (FDA/CDER) [E] [b6]; Harrigan, Rachel (HHS/IOS) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Erhardt, William (HHS/IOS) [E] [b6]; Jim Neaton [E] [b6]; Davey Smith [E] [b6]
Tountas, Karen (FNIH) [T] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Wachtel, Jonathan <jwachtel@DELOITTE.com>; Chen, Helen Q.

<qingchen@deloitte.com>; Payton, Manizhe (NIH/NIAID) [E] [b6] Adedeji, Bola (NIH/NIAID) [E]
[b6] >; Culp, Michelle (NIH/OD) [E] [b6] >; Bozzette, Sam (NIH/NCATS) [E]
[b6] >; Jonson, Samantha (NIH/NCATS) [E] [b6]

Subject: RE: Discussion about Short Site Survey to Determine COVID Trial Burden

OK, here is what I came up with. Please let me know any major adjustments or things I forgot before I send to Francis and Janet. FYI I tried to lay this out as a logically/rhetorically sequenced argument rather than just record what people said in the order they said it. David

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/18/2020 6:44:53 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: NIH-ACTIV Clinical Trial Matrix
Attachments: DRAFT ACTIV Checkerboard_9.18.20 updated 2pm.pptx

Sorry something strange happened – please try this one!

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, September 18, 2020 2:29 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: NIH-ACTIV Clinical Trial Matrix

Good afternoon,

For your awareness, the ACTIV therapeutics clinical WG provided feedback on the clinical trial matrix – attached is the most recent version with revisions including logos to indicate completed trials. We will continue to update as trials continue to launch and complete.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/18/2020 1:25:42 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Recruiting participants in outpatient COVID trials

Friendly reminder...

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, September 14, 2020 7:52 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Patterson, Amy (NIH/NHLBI) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Subject: RE: Recruiting participants in outpatient COVID trials

I'm reluctant to send the list to Brett until we have something ready that he can ask the testing centers to use to direct those who test positive to one of our trials. That's being worked on but isn't quite there.

Please remind me by the end of the week.

Francis

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, September 14, 2020 6:04 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Patterson, Amy (NIH/NHLBI) [E] [b6]
Subject: RE: Recruiting participants in outpatient COVID trials

Hi Francis,

I am circling back on the list of outpatient sites the ADM requested.

ACTIV 4 pre-hospital still does not have a list of sites outside of Florida – In Florida they are using Florida ONE system. Sites are actively being added – we can circle back once we know more but I wanted to close the loop since I know you need to get this list to Brett.

Cc'ing Amy in case you have additional questions.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Friday, September 11, 2020 10:21 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Fleurence, Rachael (NIH/OD) [C] [b6]; Tromberg, Bruce (NIH/NIBIB) [E] [b6]; Bright, Rick (NIH/OD) [E] [b6]; Heemskerk, Jill (NIH/NIBIB)

[E] [b6] Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: Recruiting participants in outpatient COVID trials

Thanks, Ashley. If you can get sites for ACTIV-4 to add to these, that would be great!

FC

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Friday, September 11, 2020 5:59 PM

To: Collins, Francis (NIH/OD) [E] [b6] Burklow, John (NIH/OD) [E] [b6]

Cc: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6];

[b6]; Fleurence, Rachael (NIH/OD) [C] [b6]; Tromberg, Bruce (NIH/NIBIB) [E] [b6]; Bright, Rick (NIH/OD) [E] [b6]; Heemskerk, Jill (NIH/NIBIB) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: Recruiting participants in outpatient COVID trials

Hi Francis and John,

If helpful attached is a list of sites for ACTIV-2, C3PO, and ITAC outpatient trials. This does not include sites for the ACTIV-4 outpatient trial but I am happy to circle back with Amy if needed.

Hopefully this is a good start.

Thanks,
Ashley

From: Burklow, John (NIH/OD) [E] [b6] v>

Sent: Friday, September 11, 2020 5:13 PM

To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6];

[b6]; Parker, Ashley (NIH/OD) [E] [b6]; Fleurence, Rachael (NIH/OD) [C] [b6]; Tromberg, Bruce (NIH/NIBIB) [E] [b6]; Bright, Rick (NIH/OD) [E] [b6]; Heemskerk, Jill (NIH/NIBIB) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: Re: Recruiting participants in outpatient COVID trials

Thanks, Francis. We are in discussions with Chris Shreeve, who, as you know, is coming on board to work with Janet Woodcock, and Michael Pratt in ASPA about how to quickly develop a common portal for the public. So far, we have a possible candidate company that has already been involved in OWS that may be able to adapt an existing tool for these purposes. We will know more early next week. I'm confident that we have access to the necessary resources to make it happen. I will let you know if that's not the case.

Thanks again,

John

John

Sent from my iPhone

On Sep 11, 2020, at 4:43 PM, Collins, Francis (NIH/OD) [E] b6 wrote:

Hi all,

As you all know, recruiting participants in COVID outpatient trials (for mAbs, convalescent plasma, antithrombotics,..) is turning out to be quite a challenge. And yet we know that ~30,000 new cases are diagnosed every day in the US. That ought to be a terrific cohort of just-diagnosed individuals who might be interested in what's available.

Right now, a missed opportunity happens when a positive test result is delivered – ideally that should be accompanied by information about available clinical trials, or at least a portal that the person could go to and explore what might be available. But testing centers have apparently been reluctant to get involved, fearful that they will be seen as endorsing particular trials, and not wanting to be liable.

But in speaking with Admiral Giroir today, he says there are 720 pharmas that do testing, plus a bunch of surge sites, that are funded directly by his office, and he could basically insist that they provide this information to anyone who tests positive. He thinks the 1900 CVS pharmas would be likely to follow suit. It would be of great interest to do a crosswalk of those locations with the recruitment sites for all of the COVID outpatient trials. Brett asked for the list of clinical trial sites, and said he could then quickly identify the testing sites that are in the same general geographic region.

If we had that info, what we then need is the information that they should distribute. This brings me to that one-stop shopping portal for the public that I know John and Renate are working on, together with OWS colleagues. How is that coming? Is there something I can do to help?

Francis

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/18/2020 6:39:36 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: FW: NIH-ACTIV Clinical Trial Matrix
Attachments: DRAFT ACTIV Checkerboard_9.18.20 updated 2pm.pptx

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, September 18, 2020 2:29 PM
To: Collins, Francis (NIH/OD) [E] [b6] Tabak, Lawrence (NIH/OD) [E] [b6]
Freire, Maria (FNIH) [T] [b6] Wholley, David (FNIH) [T] [b6] Lane, Cliff (NIH/NIAID) [E]
[b6] Austin, Christopher (NIH/NCATS) [E] [b6] Anderson, James (NIH/OD) [E]
[b6]
Cc: Adam, Stacey (FNIH) [T] [b6] Menetski, Joseph (FNIH) [T] [b6] Brodd, Lauren (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6] Myles, Renate (NIH/OD) [E]
[b6]
Subject: NIH-ACTIV Clinical Trial Matrix

Good afternoon,

For your awareness, the ACTIV therapeutics clinical WG provided feedback on the clinical trial matrix – attached is the most recent version with revisions including logos to indicate completed trials. We will continue to update as trials continue to launch and complete.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/9/2020 3:03:20 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: DRAFT NIH and ACTIV Clinical Trial Grid

Thanks, Maria!

Ashley

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, September 9, 2020 10:52 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: DRAFT NIH and ACTIV Clinical Trial Grid

Thank you Ashley! It looks good to me but then again, the WG rules. Best, M.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, September 8, 2020 12:54 PM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: DRAFT NIH and ACTIV Clinical Trial Grid

Good afternoon,

I hope everyone had a great holiday. I know there was interest from the Tx clinical WG to review the NIH and ACTIV clinical trial grid. Attached is a version that does not display agents/trial information that has not yet launched but has a placeholder for those trials "coming soon."

Please note this is still a working draft as we continue to add trials as they launch (agents for ACTIV-4 inpatient trial will be included once the trial launches this week).

We standby for any major edits the WG may have.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 9/12/2020 4:50:32 PM
To: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]
Subject: Re: Recruiting participants in outpatient COVID trials

Sounds good! Sorry, I thought you were asking for the list of sites for the ACTIV inpatient trials, which I currently do not have and thought we could pull from [CT.gov](#) if needed. I will circle back with the group once I hear from Amy about ACTIV-4 sites.

Thanks,
Ashley

On Sep 12, 2020, at 10:35 AM, Myles, Renate (NIH/OD) [E] [b6] wrote:

Thanks, Ashley. And FC doesn't want to point people to [CT.gov](#) because the string we have on [COVID-19 trials](#) includes a ton of small trials. He wants to point folks to the main trials. We had talked about having a central portal like COVPN but for therapeutics and possibly a registry with a service center so that people and physicians can be connected (like [match.com](#) for trials). Although the latter sounds like a heavy lift that would take a lot of time, which we don't have. We might have to settle with pointing them to [CT.gov](#) for the specific trials that we have listed on the site.

I can envision a portal that has:

I have never had COVID-19 and would like to participate in a prevention trial (go to COVPN)
I tested positive for COVID-19, but don't require hospitalization (go here)
I'm a physician with a hospitalized COVID-19 patient (go here)

The last two would go to pages that would further triage based on type and severity of symptoms (or something like that). We'd need help from a scientist to parse it appropriately. They could go to pages similar to this one: <https://www.coronaviruspreventionnetwork.org/understanding-clinical-studies/>

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Saturday, September 12, 2020 10:15 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E]
Subject: Re: Recruiting participants in outpatient COVID trials

Most of the concerns are low enrollment in the outpatient trials. Connecting patients once they test positive in outpatient settings to the available trials is one strategy to increase enrollment.

For the action item below, I've asked Amy for the list of sites for the ACTIV-4 outpatient trial — the ADM is interested in having this list for matching with outpatient testing sites funded by his office.

For the central portal page, I agree all trials should be included — I do not have the sites for ACTIV-3 or ACTIV-4 inpatient trials although it may be posted on [CT.gov](https://www.ct.gov). We would need the sites for ACTIV-1 and ACTIV-5 inpatient trials once they've launched if the plan is to include a link to trial locations for physicians. NCATS is funding the inpatient convalescent plasma trial if we're including CP trials on the central portal (I have a email thread with the recruiting hospitals). I prefer to ask the ICs for the sites considering [CT.gov](https://www.ct.gov) is not always up to date!

We can begin asking Stacey Adam or Cliff Lane for the ACTIV-3 sites or pull from [CT.gov](https://www.ct.gov) and confirm with NIAID/FNIH, Chris Austin for ACTIV-1, and I could easily ask Amy Patterson for the ACTIV-4 inpatient sites.

Let me know how you would prefer we handle. I'm still waiting to hear back from Amy.

Thanks,
Ashley

On Sep 12, 2020, at 9:03 AM, Myles, Renate (NIH/OD) [E] [b6] wrote:

Got it! I'm assuming we'll want to have a button where physicians can find inpatient trials too, right? Do you have a list of the ACTIV-3 and ACTIV-4?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, September 11, 2020 10:57:27 PM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]
Subject: Re: Recruiting participants in outpatient COVID trials

Hi Renate,

These are not ACTIV trials but COVID trials for outpatients. C3PO is a convalescent plasma trial for outpatients funded by NHLBI and ITAC is the IVIg study sponsored by NIAID but this hasn't launched yet.

Thanks,
Ashley

On Sep 11, 2020, at 10:46 PM, Myles, Renate (NIH/OD) [E] [b6] wrote:

Hi Ashley:

I have to be honest, I'm not familiar with terms C3PO and ITAC. Are those part of ACTIV?

Renate

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, September 11, 2020 5:59 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David

(FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E]
[b6]; Austin, Christopher (NIH/NCATS) [E]
[b6]; Freire, Maria (FNIH) [T] [b6]
Lane, Cliff (NIH/NIAID) [E] [b6] Anderson, James
(NIH/OD) [E] [b6] Fleurence, Rachael (NIH/OD)
[C] [b6]; Tromberg, Bruce (NIH/NIBIB) [E]
[b6]; Bright, Rick (NIH/OD) [E]
[b6]; Heemskerk, Jill (NIH/NIBIB) [E]
[b6]; Schwetz, Tara (NIH/OD) [E]

Subject: RE: Recruiting participants in outpatient COVID trials

Hi Francis and John,

If helpful attached is a list of sites for ACTIV-2, C3PO, and ITAC outpatient trials. This does not include sites for the ACTIV-4 outpatient trial but I am happy to circle back with Amy if needed.

Hopefully this is a good start.

Thanks,
Ashley

From: Burklow, John (NIH/OD) [E] [b6]
Sent: Friday, September 11, 2020 5:13 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David
(FNIH) [T] [b6] Tabak, Lawrence (NIH/OD) [E]
[b6]; Austin, Christopher (NIH/NCATS) [E]
[b6] Freire, Maria (FNIH) [T] [b6]
Lane, Cliff (NIH/NIAID) [E] [b6] Anderson, James
(NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]
[b6] Fleurence, Rachael (NIH/OD) [C]
[b6]; Tromberg, Bruce (NIH/NIBIB) [E]
[b6]; Bright, Rick (NIH/OD) [E]
[b6]; Heemskerk, Jill (NIH/NIBIB) [E]
[b6]; Schwetz, Tara (NIH/OD) [E]

Subject: Re: Recruiting participants in outpatient COVID trials

Thanks, Francis. We are in discussions with Chris Shreeve, who, as you know, is coming on board to work with Janet Woodcock, and Michael Pratt in ASPA about how to quickly develop a common portal for the public. So far, we have a possible candidate company that has already been involved in OWS that may be able to adapt an existing tool for these purposes. We will know more early next week. I'm confident that we have access to the necessary resources to make it happen. I will let you know if that's not the case.

Thanks again,

John

John

Sent from my iPhone

On Sep 11, 2020, at 4:43 PM, Collins, Francis (NIH/OD)
[E] [b6] wrote:

Hi all,

As you all know, recruiting participants in COVID outpatient trials (for mAbs, convalescent plasma, antithrombotics,...) is turning out to be quite a challenge. And yet we know that ~30,000 new cases are diagnosed every day in the US. That ought to be a terrific cohort of just-diagnosed individuals who might be interested in what's available.

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Francis

<NIH_ACTIV Sites of Outpatient Clinical Trials.xlsx>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 3/4/2021 2:15:49 PM
To: Bugin, Kevin [b6]
Subject: RE: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Wow – got it, thanks!

From: Bugin, Kevin [b6]
Sent: Thursday, March 4, 2021 8:36 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Yes. That is really only the short list of those heavily lifting at the moment. It is a huge group!

- Eakin, Ann (NIH/NIAID) [E]
- Adams, Peter (OS/ASPR/BARDA)
- Armstrong, Kimberly (OS/ASPR/BARDA)
- Boucher, David (OS/ASPR/BARDA)
- El Kassar, Nahed (NIH/NHLBI) [E]
- Bruno, Robert (OS/ASPR/BARDA) (CTR)
- Byun, Nellie (OS/ASPR/BARDA)
- Diaz-Diaz, Carol (OS/ASPR/BARDA)
- Erlandson, Karl (OS/ASPR/BARDA)
- Formentini, Elizabeth (OS/ASPR/BARDA)
- Herring, Kristen (OS/ASPR/BARDA)
- Horwith, Gary (OS/ASPR/BARDA)
- Hughes, Claiborne (OS/ASPR/BARDA)
- Jayashankar, Lakshmi (OS/ASPR/BARDA)
- Johnson, Robert (OS/ASPR/BARDA)
- Kozak, Marina (OS/ASPR/BARDA)
- Marks, Gilbert (OS/ASPR/BARDA) (CTR)
- Miknyoczki, Sheila (OS/ASPR/BARDA)
- Mu, Lillian (OS/ASPR/BARDA) (CTR)
- Newland, Matthew (OS/ASPR/BARDA)
- O'rourke, Anna (OS/ASPR/BARDA) (CTR)
- Oshansky, Christine (OS/ASPR/BARDA)
- [b6]
- Rao Prakash (OS/ASPR/BARDA) (CTR)
- Smith, Ashley (OS/ASPR/BARDA)
- Tse, Brian (OS/ASPR/BARDA)
- Walker, Robert (OS/ASPR/BARDA)
- Wolling, Brenda (OS/ASPR/BARDA) (CTR)
- Wu, Qun (OS/ASPR/BARDA)
- Collins, Jennifer (CDC/DDID/NCEZID/DFWED)
- Epstein, Lauren H. (CDC/DDID/NCEZID/DHQP)
- Uyeki, Timothy M. (CDC/DDID/NCIRD/ID)
- [b6]
- [b6]
- [b6]

- **b6**
- Jenkins, Amy (DARPA)
- Melissa Stamand
- Renee Wegrzyn
- **b6**
- Jennifer Kishimori

b6

- Matt Hepburn

b6

- Birnkrant, Debra B (FDA/CDER)
- Deming, Damon (FDA/CDER)
- Donaldson, Eric (FDA/CDER)
- Ellis, Christopher (FDA/CDER)
- Ghantous, Hanan (FDA/CDER)
- Komatsu, Takashi E (FDA/CDER)
- McMillan, David (FDA/CDER)
- Murray, Jeffrey S (FDA/CDER)
- Myers, Laine Peyton (FDA/CDER)
- O'Rear, Julian (FDA/CDER)
- Farley, John (FDA/CDER)
- Styrt, Barbara (FDA/CDER)
- Weinstein, Edward (FDA/CDER)
- Fisher, Robert (FDA/OC)
- Mair, Michael (FDA/OC)
- Rosenberg, Amy (FDA/CDER)
- Poley, Gerald (FDA/CDER)
- Becker, Patrice (NIH/NIAID) [E]
- Beigel, John (NIH) [E]
- Bok, Karin (NIH/VRC) [E]
- Cassetti, Cristina (NIH/NIAID) [E]
- Davey, Richard (NIH/NIAID) [E]
- Davis, Mindy (NIH/NIAID) [E]
- De wit, Emmie (NIH/NIAID) [E]
- Embry, Alan (NIH/NIAID) [E]
- Florence, Clint (NIH/NIAID) [E]
- Goldmuntz, Ellen (NIH/NIAID) [E]
- Higgs, Elizabeth (NIH/NIAID) [E]
- Kiley, James (NIH/NHLBI) [E]

- Kim, Peter (NIH/NIAID) [E]
- Lerner, Andrea (NIH/NIAID) [E]
- Leyva, Francisco (NIH/NIAID) [E]
- Mc Neeley, David (NIH/NIAID) [E]
- Marovich, Mary (NIH/NIAID) [E]
- Marston, Hilary (NIH/NIAID) [E]
- Raterman, Erica (NIH/NIAID) [E]
- Roberts, Chris (NIH/NIAID) [E]
- Read, Sarah (NIH/NIAID) [E]
- Zeituni, Erin (NIH/NIAID) [E]
- [b6]
- Bonomo, Robert (VA)
- Victoria Davey (VA)
- [b6]
- Cho, David S (CBER) (FDA/CBER)
- Talmadge, Andrew J CTR OSD OUSD A-S (USA)
- Kilgore, Nicole R CIV USARMY (USA)
- Berst, Kathleen L CIV DHA AD MGMT CAE (USA)
- McClure-Begley, Tristan
- Kilpatrick, Elizabeth (contr-bto)
- Poss, Zachary (contr-bto)
- Kost, Gina (contr-bto)
- Sciotti, Rick (NIH/NIAID) [E]
- Teyhen, Deydre (HHS/IOS)
- Myers, Tiffani (NIH/NHLBI) [C]
- [b6]
- Homer, Mary (OS/ASPR/BARDA)
- Kurilla, Michael (NIH/NCATS) [E]
- Punturieri, Antonello (NIH/NHLBI) [E]
- Bergmann-Leitner, Elke S CIV USARMY FUTURES COMMAND (USA)
- Dunsmore, Sarah (NIH/NCATS) [E]
- Hoffman, Corey (OS/ASPR/BARDA)
- Timothy Burgess
- Eldadah, Basil (NIH/NIA) [E]
- Romashkan, Sergei (NIH/NIA) [E]
- Riddle, David
- Anand, Vasudev (OS/ASPR/BARDA) (CTR)
- Swisher, Jennifer (FDA/CDER)
- Roney, Paul (OS/ASPR/BARDA)
- Guillermo, Tous (HHS)
- Latriano, Louise (OS/ASPR/BARDA)
- Dieffenbach, Carl (NIH/NIAID) [E]
- Gama, Lucio (NIH/VRC) [C];

Kevin

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Wednesday, March 3, 2021 8:22:32 PM

To: Bugin, Kevin [b6]

Subject: Re: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

I didn't recognize most of these names and seems this is primarily BARDA, are there any other NIH contacts other than Ann Eakin?

Thanks,
Ashley

On Mar 3, 2021, at 4:31 PM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Thanks, Kevin – we greatly appreciate the insight.

Ashley

From: Bugin, Kevin [b6]
Sent: Wednesday, March 3, 2021 4:25 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Hi Ashley,

Yes, rest assured its still us. We've been working on this effort (creating a portfolio of USG supported COVID-19 Tx and conducting the gaps analysis) for about a month now. In terms of the main POCs who are leading this effort, they are:

- Robert Fisher
- Elke Bergmann-Leitner
- Ann Eakin
- Nicole Kilgore
- Karl Erlandson

The research sub-team (listed below) have also provided their expertise and review of the content:

- David Riddle
- Vasudev Anand
- Oleg Borisov
- Jennifer Swisher
- Lynn Marks
- Paul Roney
- Louise Latriano
- Gerald Poley

Janet was briefed on this effort during our 2/22 Research Core Tx meeting, where she provided some feedback on areas to deprioritize (leading to the final perspective presented in the Interagency meeting this last Monday).

Hope this is helpful. And, I assume you have the attached, but sharing again just in case its helpful.

Kevin

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, March 3, 2021 12:59 PM

APAR0000010184

To: Bugin, Kevin <[REDACTED]>
Subject: RE: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Kevin,

Thank you for clarifying. Francis briefly heard about this and wanted to know more. Do you have the roster of participants for the research response group? How long have they been meeting and who are the lead POCs?

Ashley

From: Bugin, Kevin <[REDACTED]>
Sent: Wednesday, March 3, 2021 12:49 PM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Subject: RE: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Hi Ashley,

That effort is part of the USG COVID-19 Response Research sub-team of the Therapeutics side of the response. It is not part of the lessons learned. We are nearing the end of support for the current portfolio of USG Response therapeutics and the sub-team is looking at that portfolio to identify gaps and future priorities.

Kevin

From: Parker, Ashley (NIH/OD) [E] <[REDACTED]>
Sent: Wednesday, March 3, 2021 11:15 AM
To: Bugin, Kevin <[REDACTED]>
Subject: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Kevin,

I hope all is well given the breadth of activities happening simultaneously! Thank you for sharing the fact base information, this was useful to review what was captured from the interviews.

We learned of an interagency WG meeting led by USG therapeutics that took place this past Monday focused on doing a collective review of agents currently being tested and identifying any gaps with the prioritization process. Is this group one of the three lessons learned WG's discussed with the LT that will be led by ACTIV/NIH to review and develop actions for research, scoping, and prioritization (if so I would like to join and listen-in on those) or is this something else?

Thank you,
Ashley

From: Bugin, Kevin <[REDACTED]>
Sent: Saturday, February 20, 2021 8:36 AM

To: Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Armstrong, Kimberly (OS/ASPR/BARDA) [b6]
Cc: King, Mason [b6]; Ramakrishnan, Raahul [b6]; SES USARMY DOD JPEO CBRND (USA)' [b6]
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Good morning Tx Lessons Learned Leadership Group,
Thanks for your time yesterday for the kick-off of our leadership group for the therapeutics lessons learned initiative focused on clinical evaluation. Based on our discussion it sounds like we are aligned on:

- objectives, scope, approach for working group (WG), and emerging themes.
- WG additions: TransCelerate, ACRO, Society of Clinical Research Sites, patient groups (via Duke)
 - If folks have any personal contacts at TransCelerate, ACRO, or SCRS, please let me know!
- Duke-Margolis on board with lead on breakout WG, as is ACTIV but with a different facilitator (not Stacey)
- Need to keep an eye out for internal learnings and strategy, ensure these are tracked but remain separate from external working groups

As discussed, attached please the current version of the LL fact base that has emerged from the engagements with USG to date, particularly NIH/ACTIV.

Please let me know if you have any questions.

Kevin

-----Original Appointment-----

From: Woodcock, Janet [b6]
Sent: Wednesday, February 10, 2021 1:51 PM
To: Woodcock, Janet; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Adam, Stacey J (NIH); Armstrong, Kimberly (OS)
Cc: King, Mason; Ramakrishnan, Raahul; [b6] SES USARMY DOD JPEO CBRND (USA)'
Subject: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off
When: Friday, February 19, 2021 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Webex

Purpose: Align on scope and approach for the USG COVID-19 Therapeutics Lessons Learned initiative.

-- Do not delete or change any of the following text. --

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<https://fda1.webex.com/fda> b6

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Meeting password: b6

Tap to join from a mobile device (attendees only)

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US Toll

Join by phone

b6 US Toll
US Toll Free

Toll-free calling restrictions

If you are a host, [click here](#) to view host information.

Need help? Go to <https://help.webex.com>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/31/2020 8:18:19 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: Fwd: ACTIV2 Central IRB Waiver Version 2
Attachments: ACTIV2 Central IRB Waiver_082520.pdf; ATT00001.htm

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

Begin forwarded message:

From: "Collins, Francis (NIH/OD) [E]" [b6]
Date: August 25, 2020 at 2:05:07 PM EDT
To: "Wholley, David (FNIH) [T]" [b6]
Cc: "Parker, Ashley (NIH/OD) [E]" [b6] "Wood, Gretchen (NIH/OD) [E]" [b6], "McManus, Ayanna (NIH/OD) [E]" [b6] "Freire, Maria (FNIH) [T]" [b6], "Adam, Stacey (FNIH) [T]" [b6]
Subject: RE: ACTIV2 Central IRB Waiver Version 2

Here you go.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, August 25, 2020 12:05 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6] Wood, Gretchen (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: FW: ACTIV2 Central IRB Waiver Version 2

Hi Francis:

Regarding the local IRB waiver letter for ACTIV-2: As I mentioned on the daily active call this morning we have incorporated Carrie Wolinetz's suggestions and were just checking as a courtesy with Mike Lauer to see if there were folks other than the IRB Chairs we should send this to, but it has been over a day and Mike we know is very busy with other things. We think the network leads will know where to take this, and meanwhile are getting pressure from OWS and ACTIV-2 reps to move this forward. Would it be possible therefore for you to sign this and return it to me today? Please copy Stacey Adam on the reply. Thanks, David

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 3/4/2021 1:22:32 AM
To: Bugin, Kevin (FDA/CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e98409d40a4a9880bfb9f709481e7c-BUGINK.fda]
Subject: Re: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

I didn't recognize most of these names and seems this is primarily BARDA, are there any other NIH contacts other than Ann Eakin?

Thanks,
Ashley

On Mar 3, 2021, at 4:31 PM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Thanks, Kevin – we greatly appreciate the insight.

Ashley

From: Bugin, Kevin [b6]
Sent: Wednesday, March 3, 2021 4:25 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Hi Ashley,

Yes, rest assured its still us. We've been working on this effort (creating a portfolio of USG supported COVID-19 Tx and conducting the gaps analysis) for about a month now. In terms of the main POCs who are leading this effort, they are:

- Robert Fisher
- Elke Bergmann-Leitner
- Ann Eakin
- Nicole Kilgore
- Karl Erlandson

The research sub-team (listed below) have also provided their expertise and review of the content:

- David Riddle
- Vasudev Anand
- Oleg Borisov
- Jennifer Swisher
- Lynn Marks
- Paul Roney
- Louise Latriano
- Gerald Poley

Janet was briefed on this effort during our 2/22 Research Core Tx meeting, where she provided some feedback on areas to deprioritize (leading to the final perspective presented in the Interagency meeting this last Monday).

Hope this is helpful. And, I assume you have the attached, but sharing again just in case its helpful.

Kevin

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, March 3, 2021 12:59 PM
To: Bugin, Kevin [b6]
Subject: RE: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

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Hi Kevin,

Thank you for clarifying. Francis briefly heard about this and wanted to know more. Do you have the roster of participants for the research response group? How long have they been meeting and who are the lead POCs?

Ashley

From: Bugin, Kevin [b6]
Sent: Wednesday, March 3, 2021 12:49 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Hi Ashley,

That effort is part of the USG COVID-19 Response Research sub-team of the Therapeutics side of the response. It is not part of the lessons learned. We are nearing the end of support for the current portfolio of USG Response therapeutics and the sub-team is looking at that portfolio to identify gaps and future priorities.

Kevin

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, March 3, 2021 11:15 AM
To: Bugin, Kevin [b6]
Subject: [EXTERNAL] RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hi Kevin,

I hope all is well given the breadth of activities happening simultaneously! Thank you for sharing the fact base information, this was useful to review what was captured from the interviews.

We learned of an interagency WG meeting led by USG therapeutics that took place this past Monday focused on doing a collective review of agents currently being tested and identifying any gaps with the prioritization process. Is this group one of the three lessons learned WG's discussed with the LT that will be led by ACTIV/NIH to review and develop actions for research, scoping, and prioritization (if so I would like to join and listen-in on those) or is this something else?

Thank you,
Ashley

From: Bugin, Kevin [b6]
Sent: Saturday, February 20, 2021 8:36 AM
To: Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR) [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]; Armstrong, Kimberly (OS/ASPR/BARDA) [b6]
Cc: King, Mason [b6]; Ramakrishnan, Raahul [b6]; [b6] SES USARMY DOD JPEO CBRND (USA) [b6]
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Good morning Tx Lessons Learned Leadership Group,
Thanks for your time yesterday for the kick-off of our leadership group for the therapeutics lessons learned initiative focused on clinical evaluation. Based on our discussion it sounds like we are aligned on:

- objectives, scope, approach for working group (WG), and emerging themes.
- WG additions: TransCelerate, ACRO, Society of Clinical Research Sites, patient groups (via Duke)
 - If folks have any personal contacts at TransCelerate, ACRO, or SCRS, please let me know!
- Duke-Margolis on board with lead on breakout WG, as is ACTIV but with a different facilitator (not Stacey)
- Need to keep an eye out for internal learnings and strategy, ensure these are tracked but remain separate from external working groups

As discussed, attached please the current version of the LL fact base that has emerged from the engagements with USG to date, particularly NIH/ACTIV.

Please let me know if you have any questions.

Kevin

-----Original Appointment-----

From: Woodcock, Janet [b6]
Sent: Wednesday, February 10, 2021 1:51 PM
To: Woodcock, Janet; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Adam, Stacey J (NIH); Armstrong, Kimberly (OS)
Cc: King, Mason; Ramakrishnan, Raahul; [b6] SES USARMY DOD JPEO CBRND (USA)
Subject: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off
When: Friday, February 19, 2021 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Webex

Purpose: Align on scope and approach for the USG COVID-19 Therapeutics Lessons Learned initiative.

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/31/2020 8:03:10 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: Discussion about Short Site Survey to Determine COVID Trial Burden

Thanks!

From: Culp, Michelle (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 3:52 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Discussion about Short Site Survey to Determine COVID Trial Burden

Ashley,
FYI: re FC talking to the ACTIV 2 & 3 study teams about recruitment and site activation.

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, August 31, 2020 11:15 AM
To: Higgs, Elizabeth (NIH/NIAID) [E] [b6]; McNay, Laura (NIH/NIAID) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Bugin, Kevin (FDA/CDER) [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Erhardt, William (HHS/IOS) [b6]; Jim Neaton [b6]; Davey Smith [b6]
Tountas, Karen (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Chen, Helen Q. <qingchen@deloitte.com>; Payton, Manizhe (NIH/NIAID) [E] [b6]; Adedeji, Bola (NIH/NIAID) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]
Subject: RE: Discussion about Short Site Survey to Determine COVID Trial Burden

Thanks, Libby, sure. I will be circulating the draft question list that Davey and Manizhe put together shortly. I would think Dr. Collins would just give generally emphasis, including the themes Libby raises below, but someone else would preview the actual questionnaire. I trust Stacey can work with you Libby on the TPs. Who will cover the questionnaire preview piece for each meeting?

From: Higgs, Elizabeth (NIH/NIAID) [E] [b6]
Sent: Monday, August 31, 2020 11:02 AM
To: McNay, Laura (NIH/NIAID) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Kim, Peter (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6]; Bugin, Kevin (FDA/CDER) [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Erhardt, William (HHS/IOS) [b6]; Jim Neaton [b6]; Davey Smith [b6]
Tountas, Karen (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Chen, Helen Q. <qingchen@deloitte.com>; Payton, Manizhe (NIH/NIAID) [E] [b6]; Adedeji, Bola (NIH/NIAID) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]
Subject: Re: Discussion about Short Site Survey to Determine COVID Trial Burden

Good points from Laura. Please let us know if you would like us to review Dr. Collins TP. Stacey is in a good position to do so.

Thanks

Libby

From: [b6]
Date: Monday, August 31, 2020 at 10:57 AM
To: "Wholley, David (FNIH) [T]" [b6]
Cc: "Adam, Stacey (FNIH) [T]" [b6], "Kim, Peter (NIH/NIAID) [E]" [b6], "Read, Sarah (NIH/NIAID) [E]" [b6], "Bugin, Kevin (FDA/CDER)" <kevin.bugin@fda.hhs.gov>, "Harrigan, Rachel (HHS/IOS)" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Erhardt, William (HHS/IOS)" [b6], [b6] James Neaton [b6], Davey Smith [b6], Karen Tountas [b6], "Gonzalez, Nina" <ningonzalez@deloitte.com>, "Wachtel, Jonathan" <jwachtel@deloitte.com>, "Chen, Helen Q." <gingchen@deloitte.com>, "Payton, Manizhe (NIH/NIAID) [E]" [b6], "Adedeji, Bola (NIH/NIAID) [E]" [b6], "Culp, Michelle (NIH/OD) [E]" [b6], "Bozzette, Sam (NIH/NCATS) [E]" [b6], "Jonson, Samantha (NIH/NCATS) [E]" [b6]
Subject: Re: Discussion about Short Site Survey to Determine COVID Trial Burden

Thanks David- this is terrific. I might think the message from Dr. Collins might be a bit different for each study. For ACTIV 3, our current focus is for sites to get activated and increase enrollment. I think it is less about recruitment strategies (ACTIV 2) and more about pushing to activate the sites.

Many thanks again,

Laura

On Aug 31, 2020, at 10:24 AM, Wholley, David (FNIH) [T] [b6] wrote:

Hello all

Just a brief progress update on the action items from our Friday call:

- Francis Collins is set to speak to the ACTIV-2 and -3 investigator meetings on Wednesday and Thursday of this week.
- We discussed the publicity campaign issue on a call with NIH this morning. While we agreed that a broad, global reach campaign would need to include CDC and others, we should start near-term with getting an NIH-OWS comms strategy in this area pulled together asap. Larry Tabak is pulling together a call with key NIH and OWS folks to get the ball rolling.
- I am pulling together a call with Kevin Bugin to discuss phone calls to the sites, resources required.
- Given the group's agreement to preview the information request at investigator meetings, it would be good to have a draft of the cover note and questions from Davey and Manizhe soon.

Please let me know if I missed anything. Thanks, David

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/31/2020 8:01:30 PM
To: Culp, Michelle (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e38fa37e0424217aa0a283cba9e5098-mculp]
Subject: RE: Discussion about Short Site Survey to Determine COVID Trial Burden

Thanks!

From: Culp, Michelle (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 3:21 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Gadbois, Ellen (NIH/OD) [E]
Subject: RE: Discussion about Short Site Survey to Determine COVID Trial Burden

Yes, I'll forward you emails from David that has notes about a call they had on Friday.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 2:39 PM
To: Culp, Michelle (NIH/OD) [E] [b6]
Cc: Gadbois, Ellen (NIH/OD) [E]
Subject: RE: Discussion about Short Site Survey to Determine COVID Trial Burden

Hi Michelle,

Thank you for looping me in. I saw a scheduling note and email from Stacey to include me on the invite for the ACTIV-2 meeting on Thursday at 5pm but nothing yet for ACTIV-3.

I did not know what this meeting is about but it seems they will be discussing trial needs? Please let me know if there is more background on this.

Thanks again,
Ashley

From: Culp, Michelle (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 12:50 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Gadbois, Ellen (NIH/OD) [E]
Subject: FW: Discussion about Short Site Survey to Determine COVID Trial Burden

Ashley,
I'm hoping you are already in the this loop regarding FC to speak to the ACTIV 2 & 3 study teams this week. Let me know if you need more info.
-Michelle

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, August 31, 2020 12:32 PM
To: Adam, Stacey (FNIH) [T] [b6]; Jim Neaton [b6]
Cc: Kim, Peter (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6] McNay, Laura (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6] Bugin, Kevin

(FDA/CDER) [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Erhardt, William (HHS/IOS) [b6]; Davey Smith [b6]; Tountas, Karen (FNIH) [T] [b6]; Gonzalez, Nina [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Chen, Helen Q. <qingchen@deloitte.com>; Payton, Manizhe (NIH/NIAID) [E] [b6]; Adedeji, Bola (NIH/NIAID) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]; Jens Lundgren [b6]
Subject: RE: Discussion about Short Site Survey to Determine COVID Trial Burden

Jim, I think Francis was intending to speak for no more than 5 minutes. He has only 15 minutes total time available out of his calendar, so I imagine he'd stay on for that long to field any questions. I would recommend his intro be followed by someone (you?) reviewing what the needs assessment looks like in a bit more detail and getting any further feedback. But that is up to you and Jens, as it is your meeting. David

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, August 31, 2020 12:26 PM
To: Jim Neaton [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Kim, Peter (NIH/NIAID) [E] [b6]; Higgs, Elizabeth (NIH/NIAID) [E] [b6] McNay, Laura (NIH/NIAID) [E] [b6]; Read, Sarah (NIH/NIAID) [E] [b6] Bugin, Kevin (FDA/CDER) [b6]; Harrigan, Rachel (HHS/IOS) [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Erhardt, William (HHS/IOS) [b6]; Davey Smith [b6]; Tountas, Karen (FNIH) [T] [b6]; Gonzalez, Nina <ningonzalez@deloitte.com>; Wachtel, Jonathan <jwachtel@deloitte.com>; Chen, Helen Q. <qingchen@deloitte.com>; Payton, Manizhe (NIH/NIAID) [E] [b6]; Adedeji, Bola (NIH/NIAID) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Jonson, Samantha (NIH/NCATS) [E] [b6]; Jens Lundgren [b6]
Subject: RE: Discussion about Short Site Survey to Determine COVID Trial Burden

Hi Jim,

I will let David weigh in as well, but to your question on the invite. I have already send this to Francis and a member of his team who will join for tracking.

Also, his admin has noted that they expect he will join the call for 15-20 minutes and would prefer the start of the meeting. So, yes, the initial talk would be best.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Jim Neaton [b6]
Sent: Monday, August 31, 2020 12:19 PM
Subject: Re: Discussion about Short Site Survey to Determine COVID Trial Burden

Hi David et al. - who is going to provide Dr. Collins the information to join the ACTIV-3 investigator meeting call on Wednesday at 10AM EST? Stacey?

How long should we plan for his talk? Assume it would be the initial talk?

I am copying Jens Lundgren who will be chairing the meeting.

Thanks.

Jim

On Mon, Aug 31, 2020 at 10:24 AM Wholley, David (FNIH) [T] { **b6** } wrote:

Hello, all:

Attached is the draft Needs Assessment just sent me by Davey Smith, with a few added changes by me. I'd assume this could either be sent out as something to be filled in or used as a script for a phone conversation. Can I ask you all to please review this and let Davey and me know of any recommended changes? In the interest of time, please feel free to copy all on your response. Thanks.

David Wholley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/26/2020 11:46:49 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: [for distribution] Final Slides for ACTIV LT Meeting

Yep!

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 26, 2020 7:46 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: [for distribution] Final Slides for ACTIV LT Meeting

Further clarification on the checkerboard.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 9:47 PM
To: Wholley, David (FNIH) [T] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>
Subject: RE: [for distribution] Final Slides for ACTIV LT Meeting

Yes, I will remind us. To be clear – we were unable to insert the CT grid slide in the current deck without losing the links and “hover over” effect etc. – this is the reason the slide was not included in the master.

I didn’t think it was necessary to send to the LT as a separate slide given its still draft and up for discussion but we may need to figure out a way to make this work in the future if needed in a master file.

I hope this is clear.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, August 25, 2020 8:59 PM
To: Elsaid, Olivia <oelsaid@deloitte.com>; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: [for distribution] Final Slides for ACTIV LT Meeting

Thanks, Olivia. I trust Ashley’s instincts let’s do it that way. Ashley if I do not bring this up on war room tomorrow, could you please remind us?

Cheryl, I think these can go out. Do I need to prepare the note?

From: Elsaid, Olivia <oelsaid@deloitte.com>
Sent: Tuesday, August 25, 2020 8:30 PM
To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]

Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Parker, Ashley (NIH/OD) [E]

b6

Subject: [for distribution] Final Slides for ACTIV LT Meeting

Hi David,

Please find attached the final slides for tomorrow's LT meeting. Additionally, I'm separately attaching the slide that Ashley kindly put together to show the matrix of NIH and ACTIV trials. Ashley suggested that we don't include this slide in the materials that are sent out since it is still draft and contains live links so we are planning to pull it up during the live presentation when we walk through this slide. I believe you said it will be covered after the milestone slide, but please let us know what order is preferred and we will promptly have it ready during the presentation. Let me know if you prefer anything alternative for sharing that slide.

Please let us know if you have any comments or questions before these are distributed!

@Melencio, Cheryl (FNIH) [T]— please let us know if there are any late breaking attendance RSVPs and we can update accordingly for the onscreen slides.

Thank you!

Olivia

Olivia Elsaid

Deloitte Consulting LLP

200 Berkeley Street, Boston, MA, 02116

Tel/Direct: +1 617 437 3197 | Mobile: [REDACTED] b6

oesaid@deloitte.com | www.deloitte.com

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Sent: 9/2/2020 1:59:34 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: RE: C3PO trial

Hi David and Stacey,

At the time the Abbott machines were ordered for ACTIV-2 and C3PO, HHS did not anticipate having the trials return the machines and I was told this has only been done in one situation, however decisions around this topic is in flux. HHS is having to redirect shipments to areas affected by the hurricane and pause on shipments for ACTIV-2 and C3PO next week due to the stockpile running low.

In any case, the machines received should be marked as government property and the serial numbers should be tracked. I am happy to circle back and ask HHS again if the machines will need to be returned but this is the information I received previously.

Cc'ing Amy for awareness regarding pause in shipments for C3PO next week.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, September 2, 2020 9:38 AM
To: Adam, Stacey (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: C3PO trial

Ashley may know, I don't. Copying her.

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, September 2, 2020 9:25 AM
To: Wholley, David (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: C3PO trial

Hi David,

Do you know what guidance was given to the convalescent plasma sites that received the machines?

If we don't know, I will let Sheri know that we will need to send a letter marking that they should be returned.

Thanks,
Stacey

Stacey J. Adam, PhD

Director, Cancer

Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, CAPT Sheri (HHS/IOS) [b6]

Sent: Wednesday, September 2, 2020 9:11 AM

To: Homer, Mary (OS/ASPR/BARDA) [b6]

Cc: Marks, Gilbert (OS/ASPR/BARDA) (CTR) <[b6]> Adam, Stacey (FNIH) [T] [b6]

Bujaki, Becky (HHS/IOS) [b6]

Subject: RE: C3PO trial

Hi Mary,

It is my understanding that they are property of the government and would need to be returned. I know for ACTIV-3 they are tagging them as government property for items sent to the ACTG network and the PPD funded sites.

These came via the SNS to you, my assumption is they would return to the SNS.

I've added my logistic counterpart to the query as well as Stacey who assisted in the request.

v/r,
Sheri

Sheri Parker, PMP, PhD

CAPT, MSC, USN

Therapeutics Clinical Operations Director

Operation Warp Speed

Cell: [b6]

From: Homer, Mary (OS/ASPR/BARDA) [b6]

Sent: Tuesday, September 1, 2020 3:58 PM

To: Parker, CAPT Sheri (HHS/IOS) [b6]

Cc: Marks, Gilbert (OS/ASPR/BARDA) (CTR) <[b6]>

Subject: C3PO trial

Capt Parker,

Do you happen to know who authorized giving the Abbott machines to the clinical sites for C3PO – the question has come up on whether those machines will be given to the sites or collected back up after the trial?

Mary J. Homer, PhD

Chief

Radiological and Nuclear Countermeasures

Division of Chemical, Biological, Radiological, and Nuclear Countermeasures

Biomedical Advanced Research and Development Authority (BARDA)

Office of the Assistant Secretary for Preparedness and Response

Department of Health and Human Services

O'Neill Federal Office Building, 24K13

(Classic BLUE -- PANTONE 19-4052; RGB 52:86:139))

Office: [b6]

Work Mobile: [b6]

[b6]

APAR0000010276

<< OLE Object: Picture (Device Independent Bitmap) >>



Mailing address:
330 Independence Ave, SW, Room G644
Washington, DC 20201

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/27/2020 8:03:29 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Lauren,

We don't need this until COB Friday, no later than Monday morning. I will call you now to discuss.

Thanks,
Ashley

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 4:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

I can also chat for a minute on the phone now if that's easier.

From: Brodd, Lauren (NIH/OD) [E]
Sent: Thursday, August 27, 2020 3:59 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Ashley,

When do you need this by? I have about 20 minutes now that I could work on changing the links, but then I have a call and need to do something for Jessica, so I won't be able to cross-check all of these on CT.gov until later tonight/tomorrow.

Also, do you happen to know how to change the text of the hover over? I can seem to figure out how to do that.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 3:43 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Lauren,

Dr. Collins has asked if we could make a version with "coming soon" for those trials that are not yet public. Would you be able to assist with changing the links of the agents to say "coming soon" for those trials which do not yet have a CT.gov number? Each trial with a T inside a white triangle is not yet public unless you've found updates.

I know you are working on updating the current spreadsheet with ACTIV CT information. For your reference and additions, I am also attaching the spreadsheet with the NIH ongoing and planned trials that are shaded blue on the current grid (highlighted yellow on the spreadsheet). We will need to include these in the NIH tab of the spreadsheet you are updating and look to see if CT.gov numbers are available yet. Some of these NIH trials have been funded but others were not at the time the ICs provided the spreadsheet – QVR is a good tool for checking the status if needed to confirm.

Happy to chat via phone if needed.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:28 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

This is looking good. Thinking about a way to make this of wider use without disclosing confidential information, is there a version of this grid that could have the hot links provided for trials that have already been publicly announced, but a “coming soon” link for the others?

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:23 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Francis, David, and Maria,

With many thanks to Jill, attached is a PDF version of the CT grid without the links to the confidential agents etc.

I hear the Clinical Tx WG is interested in reviewing and providing edits/additions. If the ACTIV-4/NHLBI reps on the WG would like to make changes they should work closely with Amy Patterson – the current info provided was vetted by Amy and her team.

Once the WG group has collective edits we will update those on the live version. Please let us know if this plan works for FNIH—cc’ing Stacey as well.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 3/3/2021 6:12:53 PM
To: Appell, Evan [eappell@deloitte.com]
Subject: RE: ACTIV & NIH Data Sharing and Collaboration

Received – thanks, Evan!

Ashley

From: Appell, Evan <eappell@deloitte.com>
Sent: Wednesday, March 3, 2021 11:45 AM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Subject: RE: ACTIV & NIH Data Sharing and Collaboration

Hi Ashley,

I just submitted the request through Basecamp to add you to the NIH site, so you should be receiving an email from them shortly with the link.

Let me know if you have any trouble accessing the site!

Thanks,
Evan

Evan Appell
Deloitte Consulting LLP
Mobile: [REDACTED] b6
eappell@deloitte.com

From: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Sent: Wednesday, March 3, 2021 10:49 AM
To: Appell, Evan <eappell@deloitte.com>
Subject: [EXT] RE: ACTIV & NIH Data Sharing and Collaboration

Hi Evan,

I created my basecamp account, can you please grant permission to access the “ACTIV / NIH Data Sharing & Collaboration.”

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, February 26, 2021 11:52 PM
To: Appell, Evan <eappell@deloitte.com>
Subject: RE: ACTIV & NIH Data Sharing and Collaboration

Thanks! I will let you know once I create an account on Monday.

From: Appell, Evan <eappell@deloitte.com>
Sent: Friday, February 26, 2021 5:57 PM

To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV & NIH Data Sharing and Collaboration

Hi Ashley,

Just let me know when you've created your Basecamp account and then I'll be sure to add you to the site. Hope you have a nice weekend!

Thanks,
Evan

Evan Appell
Deloitte Consulting LLP
Mobile: [b6]
eappell@deloitte.com

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, February 26, 2021 5:07 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Appell, Evan <eappell@deloitte.com>; Adam, Stacey (FNIH) [T] [b6]
Subject: [EXT] RE: ACTIV & NIH Data Sharing and Collaboration

Thanks, David!

Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, February 26, 2021 3:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Appell, Evan <eappell@deloitte.com>; Adam, Stacey (FNIH) [T] [b6]
Subject: FW: ACTIV & NIH Data Sharing and Collaboration

Hi Ashley:

As have heard on war room earlier this week, we had a request from Yves Rosenberg to access information on the agents prioritized by the ACTIV Therapeutics Working Group in order to inform prioritization discussions at NHLBI. In response the ACTIV FNIH/Deloitte team has created a shared site on a platform called Basecamp which can be used to share information between our groups on which agents have been reviewed as potential treatments / therapeutics for COVID-19. The site includes summaries of the results of the deliberations of the ACTIV Agent Prioritization Workgroup on those agents that went beyond the initial triage stage, anonymized to remove the reviewer names. Given your role and the kinds of queries about the prioritization process you get, I thought you could use access to this.

Below please find an overview of how to access the Basecamp site, along with details on the materials that have already been uploaded.

As you know, we are also granting access to specified individuals within the major ICs involved in ACTIV: NIAID, NHLBI, NINDS, and NCATS.

Please let me and Evan Appell of Deloitte Consulting know if you have any questions or difficulty accessing the site, and our team can help to troubleshoot as needed. Thanks,

David

Accessing Basecamp:

1. In order to access Basecamp, the individual must **create an account** on Basecamp (*only if you do not have a Basecamp account already)
 - This can easily be done by following this link:
https://3.basecamp.com/signup/account/new?plan=one_v1
2. Once the individual has created their account, they should inform the ACTIV team so that we can **grant them permission** to access the “**ACTIV / NIH Data Sharing & Collaboration**” Basecamp site
 - The individual will then receive an email **directly from Basecamp** (not from FNIH) alerting them that they have been given access to the “**ACTIV / NIH Data Sharing & Collaboration**” Basecamp site
3. Once the individual has been granted permission to the site, they can **access it through the email that was sent to them or by following this link:** <https://3.basecamp.com/3948057/projects/21021910>

Materials Available on the Basecamp site:

4. Once an individual enters the “**ACTIV / NIH Data Sharing & Collaboration**” Basecamp site, they will see a “**Docs & Files**” folder which contains a **PowerPoint file** titled “**ACTIV_TX-Preclinical and Clinical_Agent Prioritization Summary_vSHARE**”
 - They can then download this file from Basecamp, and view it on their desktop app
5. The file includes a **summary of all agents that have been reviewed** by the ACTIV Therapeutics-Clinical Agent Prioritization Sub Teams.
A few brief notes on what is included in this file:
 - There are ~200 reviews of Antiviral, Immune Modulator, and Symptomatic / Supportive agents that have been evaluated by ACTIV
 - We have included a summary of the scoring criteria that were used to assess each agent at the very front of the deck
 - There is a table of contents in the beginning of the deck listing all of the agents that have been reviewed (which also includes hyperlinks that can be used to navigate directly to the detailed review of any particular agent)

David Wholley

**Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health**

(301) 594-6343 | fnih.org

11400 Rockville Pike Suite 600 North Bethesda, MD 20852



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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/31/2020 11:46:03 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: Re: Sites and Locations for ACTIV-2

Yes, will do. Thanks, Stacey.

Ashley

On Aug 31, 2020, at 7:37 PM, Adam, Stacey (FNIH) [T] [b6] wrote:

Hi Ashley,

Here is the updated ACTIV-2 Potential Site list. Not in the template, but should have all you would need. If you can, I would strip out any rows that you do not need to send to HRSA.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Smith, David: [b6]
Sent: Monday, August 31, 2020 6:45 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Fw: Sites and Locations for ACTIV-2

Hi Stacey

Attached is the list of ALL sites in various states of activation. The list of ACTG domestic sites are embedded here:

PI Name	Institution	Site #	ACTG Site	City	State
Arduino, Roberto	Lyndon B. Johnson Hospital	1014	X 31473	Houston	TX
Aziz, Mariam	Rush University Medical Center	1017	X 2702	Chicago	IL
Bedimo, Roger	Trinity Health and Wellness Center - (CRS)	1030	X - 31443	Dallas	TX
Benson, Constance	University of California San Diego AVRC	1002	X 701	San Diego	CA
Campbell, Thomas	University of Colorado	1007	X 6101	Aurora	CO

Chew, Kara	University of California Los Angeles	1003	X 601	Los Angeles	CA
Choudhary, Madhu	The University of Pittsburgh	1018	X 1001	Pittsburgh	PA
Collier, Ann	University of Washington AIDS Clinical Trials	1012	X 1401	Seattle	WA
Daar, Eric	Harbor UCLA - (CRS)	1022	X 603	Torrance	CA
Del Rio, Carlos	The Ponce de Leon Center - (CRS)	1015	X 5802	Atlanta	GA
Dooley, Kelly	Johns Hopkins University	1006	X 201	Baltimore	MD
Evering, Teresa	Cornell Clinical Trials Unit, New York Presbyterian Hospital-Weill Cornell Uptown CRS	1011	X 7803	New York	NY
Fichtenbaum, Carl	Cincinnati CRS	1004	X 2401	Cincinnati	OH
Finkel, Diana	New Jersey Medical School Clinical Research Center CRS	1021	X32759	Newark	NJ
Gandhi, Rajesh	Massachusetts General Hospital	1016	X 101	Boston	MA
Haas, David	Vanderbilt Therapeutics	1013	X 3652	Nashville	TN
Henn, Sarah	Whitman-Walker Health - (CRS)	1027	X 31791	Washington	DC
Jacobson, Jeffrey	Case Western Reserve University	1033	X 2501	Cleveland	OH
Keefer, Michael	University of Rochester - PPDS	1010	X 31787	Rochester	NY
Luetkemeyer, Anne	University of California San Francisco	1009	X 801	San Francisco	CA
Malvestutto, Carlos	Ohio State University Medical Center	1020	X 2301	Columbus	OH
Overton, Edgar	University of Alabama at Birmingham	1005	X 31788	Birmingham	AL
Presti, Rachel	Washington University School of Medicine	1008	X 2101	Saint Louis	MO
Santana-Bagur, Jorge	Puerto Rico AIDS Clinical Trials Unit - (CRS)	1024	X 5401	San Juan	Puerto Rico
Sax, Paul	Brigham and Women's Hospital - Therapeutics Clinical Research Site (CRS)	1023	X 107	Boston	MA
Taiwo, Babefemi	Northwestern University	1025	X 2701	Chicago	IL
Tebas-Medrano	University of Pennsylvania	1031	X 6201	Philadelphia	PA
Van Dam, Cornelius	Greensboro CRS	1034	X 3203	Greensboro	NC

Wohl, David	University of North Carolina at Chapel Hill	1001	X 3201	Chapel Hill	NC
Yin, Michael (previously Sobieszczyk, Magdalena)	Columbia University Irving Medical Center	1019	X 30329	New York	NY

Let me know if you have any questions
Davey

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, August 31, 2020 10:31 AM
To: [b6]; Jhoanna Roa [b6]; Currier, Judith, M.D. [b6] Smith, David [b6]
Cc: Erhardt, William (HHS/IOS) [b6]
Subject: FW: Sites and Locations for ACTIV-2

Hi Peter, Jhoanna, Davey, and Judy,

I have a list of the approved ATCG sites that I could send Ashley in lieu of this template, but it is only 15 sites. Do you have a comprehensive list of all the sites under consideration for ACTIV-2 that I could give Francis's team today.

BTW, if you have already generated this for Sheri Parker and the OWS team, please just send me that same list. Please don't recreate the wheel.

Above, all I want to note we don't need to fill out this template if we have the information in another useable format.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 1:25 PM
To: Adam, Stacey (FNIH) [T] [b6] Wholley, David (FNIH) [T] [b6]
Subject: Sites and Locations for ACTIV-2

Hi Stacey and David,

We are working to get additional assistance with space/mobile units for the ACTIV outpatient trials. In an effort to match locations of the mobile units we need the list of institutional sites and locations for ACTIV-2.

Attached is a template, Stacey do you have the contacts that can help provide us with the list? Would they be able to gather this information by COB today?

Thanks,
Ashley

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<OWS_ACTIV2_Site Status Update_incl_potentials_31Aug2020.xlsx>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/24/2020 12:18:57 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bff4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi David,

Thank you and the FNIH team – we will include the edits. We used ACTIV-like to keep the text inside the box (ACTIV-associated was long) and I've seen ACTIV-like used in previous communication docs but we can try to adjust.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, August 24, 2020 7:45 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: FW: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi, great work. Since you asked for reactions:

Please see version from Stacey with some fixes in some of the names and a comment for correction on ACTIV-1's classification. Also two observations from me and Mike Santos:

- 1) Why are the four vaccines listed a different color than the "NIH-funded studies?" Is not that, courtesy of CoVPN, what they are?
- 2) I think the term "ACTIV-like" sounds weak and awkward compared to "ACTIV-Associated" Who made the decision to use the former?

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/24/2020 12:07:56 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: FW: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE
Attachments: DRAFT NIH_ACTIV Checkerboard_8.14.20 630PM-sja.pptx

We can discuss after the call.

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, August 24, 2020 7:45 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: FW: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

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- 1) Why are the four vaccines listed a different color than the "NIH-funded studies?" Is not that, courtesy of CoVPN, what they are?
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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 3/3/2021 4:14:44 PM
To: Bugin, Kevin [b6]
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Flag: Follow up

Hi Kevin,

I hope all is well given the breadth of activities happening simultaneously! Thank you for sharing the fact base information, this was useful to review what was captured from the interviews.

We learned of an interagency WG meeting led by USG therapeutics that took place this past Monday focused on doing a collective review of agents currently being tested and identifying any gaps with the prioritization process. Is this group one of the three lessons learned WG's discussed with the LT that will be led by ACTIV/NIH to review and develop actions for research, scoping, and prioritization (if so I would like to join and listen-in on those) or is this something else?

Thank you,
Ashley

From: Bugin, Kevin [b6]
Sent: Saturday, February 20, 2021 8:36 AM
To: Woodcock, Janet (FDA/OC) [b6]; Marks, Gilbert (OS/ASPR/BARDA) (CTR)
[b6]; Parker, Ashley (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T]
[b6]; Armstrong, Kimberly (OS/ASPR/BARDA) [b6]
Cc: King, Mason [b6]; Ramakrishnan, Raahul [b6]; [b6] SES
USARMY DOD JPEO CBRND (USA) [b6]
Subject: RE: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

Good morning Tx Lessons Learned Leadership Group,

Thanks for your time yesterday for the kick-off of our leadership group for the therapeutics lessons learned initiative focused on clinical evaluation. Based on our discussion it sounds like we are aligned on:

- objectives, scope, approach for working group (WG), and emerging themes.
- WG additions: TransCelerate, ACRO, Society of Clinical Research Sites, patient groups (via Duke)
 - If folks have any personal contacts at TransCelerate, ACRO, or SCRS, please let me know!
- Duke-Margolis on board with lead on breakout WG, as is ACTIV but with a different facilitator (not Stacey)
- Need to keep an eye out for internal learnings and strategy, ensure these are tracked but remain separate from external working groups

As discussed, attached please the current version of the LL fact base that has emerged from the engagements with USG to date, particularly NIH/ACTIV.

Please let me know if you have any questions.

Kevin

-----Original Appointment-----

From: Woodcock, Janet [b6]
Sent: Wednesday, February 10, 2021 1:51 PM

APAR0000010434

To: Woodcock, Janet; Bugin, Kevin; Marks, Gilbert L (OS); Parker, Ashley S (NIH); Adam, Stacey J (NIH); Armstrong, Kimberly (OS)

Cc: King, Mason; Ramakrishnan, Raahul; [b6] SES USARMY DOD JPEO CBRND (USA)'

Subject: USG COVID-19 Therapeutics Lessons Learned Leadership Group – Kick-off

When: Friday, February 19, 2021 1:30 PM-2:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Webex

Purpose: Align on scope and approach for the USG COVID-19 Therapeutics Lessons Learned initiative.

— Do not delete or change any of the following text. —

When it's time, join your Webex meeting here.

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<https://fda1.webex.com/>

[b6]

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Meeting number (access code):

[b6]

Meeting password:

[b6]

Tap to join from a mobile device (attendees only)

[b6]

US Toll Free

US Toll

Join by phone

[b6]

US Toll

US Toll Free

Toll-free calling restrictions

If you are a host, click [here](#) to view host information.

Need help? Go to <https://help.webex.com>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 1/13/2021 1:44:02 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: FW: CONFIDENTIAL: RA Materials for today's OWS Board Meeting
Attachments: 2021-01-07 OWS board briefing Vx Tx overview Final.pdf

Please do not share.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, January 7, 2021 10:52 AM
To: Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: CONFIDENTIAL: RA Materials for today's OWS Board Meeting

Please do not distribute further.

FC

From: Tignor, Beth (HHS/IOS) [b6]
Sent: Thursday, January 7, 2021 10:27 AM
To: Tignor, Beth (HHS/IOS) [b6]
Subject: RA Materials for today's OWS Board Meeting

V/R
Beth Tignor
Director of Scheduling
The Department of Health and Human Services

[b6]

Confidential and pre-decisional communication

From: Austin, Christopher (NIH/NCATS) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=17597CABC42247548E596778304F781F-AUSTINC]
Sent: 6/19/2020 12:30:33 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: Mayo convalescent plasma results

Paper on Mayo convalescent plasma data:

https://mayoclinicproceedings.org/pb/assets/raw/Health%20Advance/journals/jmcp/jmcp_ft95_6_8.pdf

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, June 18, 2020 9:28 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];
Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire,
Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD)
[E] [b6]
Subject: ACTIV Daily Update 20200619.pptx

For tomorrow morning's war room, Friday June 19.

From: George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGEJIL]
Sent: 5/14/2020 7:14:40 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: 2020-05-13_Executive_Committee_Meeting_Summary rev2
Attachments: 2020-05-13_Executive_Committee_Meeting_Summary rev2.docx

Same file name. Note: I turned off track changes. Hope that's okay. Also, I don't understand the groupings, but I'm sure you do.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 3:06 PM
To: George, Jill (NIH/OD) [E] [b6]
Subject: FW: 2020-05-13_Executive_Committee_Meeting_Summary rev2

This Appendix B is so stubborn – I can't delete it. I want to keep the list of attendees but delete the chat box. Sorry to worry you with this – can you help at all?

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 14, 2020 2:30 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: 2020-05-13_Executive_Committee_Meeting_Summary rev2

FYI, just about ready to press send but thought I'd check to see if action items look right

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 9/8/2020 6:02:37 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
Subject: RE: DRAFT NIH and ACTIV Clinical Trial Grid

Thanks, Ashley,

We will review with the TX-Clinical WG and relay any feedback we receive to you.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, September 8, 2020 12:54 PM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]
Subject: DRAFT NIH and ACTIV Clinical Trial Grid

Good afternoon,

I hope everyone had a great holiday. I know there was interest from the Tx clinical WG to review the NIH and ACTIV clinical trial grid. Attached is a version that does not display agents/trial information that has not yet launched but has a placeholder for those trials "coming soon."

Please note this is still a working draft as we continue to add trials as they launch (agents for ACTIV-4 inpatient trial will be included once the trial launches this week).

We standby for any major edits the WG may have.

Thanks,
Ashley

From: George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGEJIL]
Sent: 8/25/2020 8:48:18 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE
Attachments: DRAFT NIH_ACTIV Checkerboard_8.25.20-445PM.pptx

I fixed the location of a few of the icons. They were "over the line." 😊

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 4:31 PM
To: George, Jill (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill and Lauren,

Many thanks for your edits and review. Additional edits are included in the attached version that I will send forward to FC and FNIH for tomorrow LT meeting.

Jill – stay tuned to how this works with FNIH's set.

Thanks again,
Ashley

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 2:27 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Fingers crossed...

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 1:50 PM
To: George, Jill (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill,

I do not have a preference here but I am inclined to keep them in the order requested to avoid having to go back and make changes again. Can we please list the antivirals + mAbs first?

Thanks,
Ashley

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 1:40 PM

To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Here you go! The rows are not in the order you had them, but I think what I've done here makes sense. If I need to change the order or make any changes, just ask!

Thanks,
Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 10:30 AM
To: George, Jill (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks, Jill.

Attached is the example of what FC is asking regarding the separation of the (combination remdesivir + mAbs) and (combination remdesivir + IVIG).

I hope this makes sense.

Thanks,
Ashley

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 3:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Good morning!

I've added the two clinical trial hyperlinks in this version. (They embedded just fine in your email Lauren 😊. Your toddler didn't eat your homework, and I'm sure is pretty darn cute even when driving you crazy.) If they need to be swapped out, no problem.

"CTL+Click to follow link" disappears when viewed as a show.

Okie dokie. This old lady got restless and came downstairs for a bit. But it's time to head back up! Hope you both are sleeping soundly —and that I return to slumberland soon.

Best,
Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 24, 2020 9:51 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: Re: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks, Lauren!

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Aug 24, 2020, at 9:14 PM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Sounds good. And sorry for the delay...my toddler was in meltdown mode tonight so I didn't get a chance to review the revised draft until after he was asleep!

I thought I included the CT hyperlinks in my email below but they might not have copied correctly (just double check to make sure these are the trials you had in mind):

AZ: NCT04516746

<https://clinicaltrials.gov/ct2/show/NCT04516746?term=NCT04516746&draw=2&rank=1>

Janssen: NCT04505722

<https://clinicaltrials.gov/ct2/show/NCT04505722?term=NCT04505722&draw=2&rank=1>

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 24, 2020 9:02 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: Re: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks, Lauren. I already sent a revised draft to FC but we still have time for edits.

I don't think the A's should have a click link but I defer to Jill on this.

If you have the links to the NCT's for the vaccine trials please send them so we can link to those. I didn't think Novavax was using the harmonized vaccine protocol but we should ask Mike Santos and find out if we need to include this one.

Thanks,
Ashley

On Aug 24, 2020, at 8:35 PM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

I also think it looks great!

This is minor and I don't know if there is a way to change it, but when you hover over the "A" for agent info, under the agent name in the box that pops up it says "CTL+Click to follow link" but those aren't actually links, correct? If so, they didn't open for me, and if not, maybe that text could be deleted.

For the vaccines, would the Novavax vaccine fall into this category (because of the OWS funding announcement)?

Also for the vaccines, I recently saw the AZ and Janssen phase 3 trails posted on CT.gov if you want to include those.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 24, 2020 6:11 PM
To: George, Jill (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks!!

From: George, Jill (NIH/OD) [E] [b6]
Sent: Monday, August 24, 2020 6:06 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Ashley,
With a few tweaks. Looks great (IMHO).
Thanks,
Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 24, 2020 5:31 PM
To: George, Jill (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill and Lauren,

Please see attached edits. Let me know what you think.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, August 24, 2020 2:37 PM
To: George, Jill (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill,

A few more:

- Rename mAbs to Neutralizing monoclonal antibodies (mAbs)

- Move the mAb NIH trial for hospitalized non-ventilated, agent; Tocilizumab to hospitalized non-ventilated to share box with other immune modulators (ACTIV-1 and NIH trial)

Thanks!
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, August 24, 2020 10:07 AM
To: George, Jill (NIH/OD) [E]; [b6]
Cc: Brodd, Lauren (NIH/OD) [E]; [b6]
Subject: Re: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill,

Per our discussion: the following changes are needed.

- Add hover over NIH logo to display the IC which funded or planning to fund the trial
- ACTT trials should be renamed with NIH logo with NIAID as hover over display
- Vaccine trials should be renamed as USG with hover over logo to show company/industry name
- CP trials for prevention, outpatient asym., and outpatient sym. to be renamed as USG with DOD as hover over
- ACTIV trials should now have the same color
- ACTIV-1 trial to move from immunomodulator to share box with ACTT-3 (to be updated to NIH trial) and the agent for ACTIV-1 to be updated to show Remdesivir plus Abatacept; Remdesivir plus Cenicriviroc; Remdesivir plus Infliximab
- Let's change ACTIV-like 6 to ACTIV-Associated trial
- Add [CT.gov](#) links to ACTIV-2 [NCT04518410](#)
- Add [CT.gov](#) links to ACTIV-3 [NCT04501978](#)
- We should have 4 colors: NIH trials, USG trials, ACTIV, and ACTIV-Associated

I am cc'ing Lauren for awareness. Lauren – we've discussed the checkerboard for future posting on the website and updates. I would like your set of eyes for review after we've included the changes.

Thanks,
Ashley

From: Wholley, David (FNIH) [T]; [b6]
Sent: Monday, August 24, 2020 7:45 AM
To: Collins, Francis (NIH/OD) [E]; [b6]; Parker, Ashley (NIH/OD) [E]
 [b6]
Cc: Freire, Maria (FNIH) [T]; [b6] Austin, Christopher (NIH/NCATS) [E]
 [b6]; Lane, Cliff (NIH/NIAID) [E]; [b6]; Anderson, James (NIH/OD) [E]; [b6]; Tabak, Lawrence (NIH/OD) [E]
 [b6]
Subject: FW: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi, great work. Since you asked for reactions:

Please see version from Stacey with some fixes in some of the names and a comment for correction on ACTIV-1's classification. Also two observations from me and Mike Santos:

- 1) Why are the four vaccines listed a different color than the "NIH-funded studies?" Is not that, courtesy of CoVPN, what they are?
- 2) I think the term "ACTIV-like" sounds weak and awkward compared to "ACTIV-Associated" Who made the decision to use the former?

From: George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGEJIL]
Sent: 8/25/2020 8:35:10 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Please strongly suggest leaving it as a separate file if they want the hover overs to work. They might be able to get it to look good, but FC may wish to demonstrate how to use it. If he is going for looks alone, I can format it now for adding to the slide set.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 4:31 PM
To: George, Jill (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill and Lauren,

Many thanks for your edits and review. Additional edits are included in the attached version that I will send forward to FC and FNIH for tomorrow LT meeting.

Jill – stay tuned to how this works with FNIH's set.

Thanks again,
Ashley

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 2:27 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Fingers crossed...

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 1:50 PM
To: George, Jill (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill,

I do not have a preference here but I am inclined to keep them in the order requested to avoid having to go back and make changes again. Can we please list the antivirals + mAbs first?

Thanks,
Ashley

From: George, Jill (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 1:40 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Here you go! The rows are not in the order you had them, but I think what I've done here makes sense. If I need to change the order or make any changes, just ask!

Thanks,
Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 10:30 AM
To: George, Jill (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks, Jill.

Attached is the example of what FC is asking regarding the separation of the (combination remdesivir + mAbs) and (combination remdesivir + IVIG).

I hope this makes sense.

Thanks,
Ashley

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Sent: Tuesday, August 25, 2020 3:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
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Sent: Monday, August 24, 2020 9:51 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: Re: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks, Lauren!

Ashley Parker, Ph.D.

Office of the Director | National Institutes of Health

Tel: [b6]

On Aug 24, 2020, at 9:14 PM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Sounds good. And sorry for the delay...my toddler was in meltdown mode tonight so I didn't get a chance to review the revised draft until after he was asleep!

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<https://clinicaltrials.gov/ct2/show/NCT04516746?term=NCT04516746&draw=2&rank=1>

Janssen: NCT04505722

<https://clinicaltrials.gov/ct2/show/NCT04505722?term=NCT04505722&draw=2&rank=1>

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Also for the vaccines, I recently saw the AZ and Janssen phase 3 trails posted on CT.gov if you want to include those.

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To: George, Jill (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Thanks!!

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Sent: Monday, August 24, 2020 6:06 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Ashley,
With a few tweaks. Looks great (IMHO).
Thanks,
Jill

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Cc: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill and Lauren,

Please see attached edits. Let me know what you think.

Thanks,
Ashley

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Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill,

A few more:

- Rename mAbs to Neutralizing monoclonal antibodies (mAbs)
- Move the mAb NIH trial for hospitalized non-ventilated, agent; Tocilizumab to hospitalized non-ventilated to share box with other immune modulators (ACTIV-1 and NIH trial)

Thanks!

Ashley

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Sent: Monday, August 24, 2020 10:07 AM

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Cc: Brodd, Lauren (NIH/OD) [E] [b6]

Subject: Re: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

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- ACTIV trials should now have the same color
- ACTIV-1 trial to move from immunomodulator to share box with ACTT-3 (to be updated to NIH trial) and the agent for ACTIV-1 to be updated to show Remdesivir plus Abatacept; Remdesivir plus Cenicriviroc; Remdesivir plus Infliximab
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- We should have 4 colors: NIH trials, USG trials, ACTIV, and ACTIV-Associated

I am cc'ing Lauren for awareness. Lauren – we've discussed the checkerboard for future posting on the website and updates. I would like your set of eyes for review after we've included the changes.

Thanks,

Ashley

From: Wholley, David (FNIH) [T] [b6]

Sent: Monday, August 24, 2020 7:45 AM

To: Collins, Francis (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E]

[b6]

Cc: Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E]

[b6]; Lane, Cliff (NIH/NIAID) [E] <[b6]>; Anderson, James (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]

[b6]

Subject: FW: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi, great work. Since you asked for reactions:

Please see version from Stacey with some fixes in some of the names and a comment for correction on ACTIV-1's classification. Also two observations from me and Mike Santos:

- 1) Why are the four vaccines listed a different color than the "NIH-funded studies?" Is not that, courtesy of CoVPN, what they are?
- 2) I think the term "ACTIV-like" sounds weak and awkward compared to "ACTIV-Associated" Who made the decision to use the former?

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Sent: 8/25/2020 8:01:35 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

I regret they ever asked for hover overs before we got closer to final content.

From: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Sent: Tuesday, August 25, 2020 3:59 PM
To: George, Jill (NIH/OD) [E] [REDACTED] b6
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Somehow many of the links and agents got mixed up. It's a ton of them and I am going through now to see if I can fix them all.

From: George, Jill (NIH/OD) [E] [REDACTED] b6
Sent: Tuesday, August 25, 2020 2:27 PM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Cc: Brodd, Lauren (NIH/OD) [E] [REDACTED] b6
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Fingers crossed...

From: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Sent: Tuesday, August 25, 2020 1:50 PM
To: George, Jill (NIH/OD) [E] [REDACTED] b6
Cc: Brodd, Lauren (NIH/OD) [E] [REDACTED] b6
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi Jill,

I do not have a preference here but I am inclined to keep them in the order requested to avoid having to go back and make changes again. Can we please list the antivirals + mAbs first?

Thanks,
Ashley

From: George, Jill (NIH/OD) [E] [REDACTED] b6
Sent: Tuesday, August 25, 2020 1:40 PM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Cc: Brodd, Lauren (NIH/OD) [E] [REDACTED] b6
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

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Thanks, Lauren!

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel [b6]

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[b6]
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Sent: 8/31/2020 10:48:39 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Great- thanks!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 6:38 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Lauren,

This looks great! I will send to Jill cc'ing you to add the two trials – JHU is part of the NCATS CTSAs, the NCT number provided below appears correct.

Thanks,
Ashley

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 4:40 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Ashley,

Attached are the updated files based on our discussion.

- Powerpoint grid: changed to "Coming soon". Ready to be sent to Jill to add the two trials (see next bullet).
- Checkerboard excel file: "grid" has two trials for Jill to add in red (with CT link in square so easier for her to add).
 - Note: after we talked, I double checked CT.gov and I found the other trial too. Line 16 on master excel file is [NCT04354155](#). As with other addition, NCATS isn't listed so you might want to verify this trial before you send to Jill.
- Master NIH trial excel: all in yellow now have ICs in red as they all are now in our file.

Let me know if you need anything else.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Sunday, August 30, 2020 2:46 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Thanks, I've updated the invite.

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Sunday, August 30, 2020 2:13 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Ashley,

My usual 11am Monday call is canceled tomorrow, so I could do anytime between 9:30-noon. Let me know what works best for you.

Thanks!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Sunday, August 30, 2020 12:38 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: NIH and ACTIV Clinical Trial Grid w/o Links

Thanks, Lauren. Let's see if we can find a time to discuss earlier on Monday rather than our usual afternoon touch base.

I'm available after 8:30am.

Thanks,
Ashley

On Aug 29, 2020, at 2:29 PM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Hi Ashley,

Attached are updated versions of the grid, CT info, and master NIH trials:

- Grid: this version has "coming soon" for trials without [CT.gov](#) info, and also has links added for any that are now on [CT.gov](#). I used the master NIH trial file to search the name/agent/IC in [CT.gov](#) but have not yet double checked in QVR.
 - For the NIAID mAb prevention square in grid, I changed the agent name to LY-CoV555 and added link [NCT04497987](#). In your last email, you said it needed to also be added for Outpatient/Asym and OP/S, but from what I could tell from the [CT.gov](#) listing, I think this trial is only for prevention, so I did not add those to the powerpoint grid. If there are additional planned studies, they could be added but I wasn't sure so just left as is.
 - In the NIAID mAb prevention square in the 'grid' tab of the excel file, I left "NIAID Agent: LY-3819258" (in red) that was in previous version because I wasn't sure if this is still being planned. The master excel sheet is a bit confusing because in line 44, AB ending in 58 is in column D but mAB ending in 53 is in columns E and G (and that is the one in [CT.gov](#)).
 - For LY3819253, [CT.gov](#) listings are NCT04518410 (ACTIV2), NCT04501978 (ACTIV3), NCT04497987 (NIAID prevention), and NCT04411628 and NCT04427501 (those two do not have NIAID involvement from what I can tell).
 - There are no [CT.gov](#) trials for LY3819258.
 - Just an FYI that for a few of a squares that have multiple trials listed and some now have links (e.g., other therapies, host non-vent), I moved the ones with the links to the top so those are before the 'coming soon'.

- CT info excel file: this has updated info on the 'grid' tab, and trial tabs. For the trial tabs, I added all those referred to on the grid (with basic info such as grid location, agent, IC, CT link if available). For those with [CT.gov](#) info now available, I have not yet added all the trial details (aside from the basics). I need to do a few things for Jessica but will work on that early next week.
- Master NIH trial file: Of the ones you highlighted in yellow, the ones that now have the IC in red are trials that have been added to the grid excel file. I know you said all the highlighted ones should be in the grid excel file, so wanted to send this to double check about the ones in yellow that I didn't change to red.

Hope that all makes sense. Let me know if you have any questions.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 3:43 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Lauren,

Dr. Collins has asked if we could make a version with "coming soon" for those trials that are not yet public. Would you be able to assist with changing the links of the agents to say "coming soon" for those trials which do not yet have a [CT.gov](#) number? Each trial with a T inside a white triangle is not yet public unless you've found updates.

I know you are working on updating the current spreadsheet with ACTIV CT information. For your reference and additions, I am also attaching the spreadsheet with the NIH ongoing and planned trials that are shaded blue on the current grid (highlighted yellow on the spreadsheet). We will need to include these in the NIH tab of the spreadsheet you are updating and look to see if [CT.gov](#) numbers are available yet. Some of these NIH trials have been funded but others were not at the time the ICs provided the spreadsheet – QVR is a good tool for checking the status if needed to confirm.

Happy to chat via phone if needed.

Thanks,
 Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 27, 2020 2:28 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
 [b6] Freire, Maria (FNIH) [T] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: RE: NIH and ACTIV Clinical Trial Grid w/o Links

This is looking good. Thinking about a way to make this of wider use without disclosing confidential information, is there a version of this grid that could have the hot links provided for trials that have already been publicly announced, but a "coming soon" link for the others?

FC

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Sent: Thursday, August 27, 2020 2:23 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6];
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Cc: George, Jill (NIH/OD) [E] [b6]; Adam, Stacey (FNIH) [T] [b6]
Subject: NIH and ACTIV Clinical Trial Grid w/o Links

Hi Francis, David, and Maria,

With many thanks to Jill, attached is a PDF version of the CT grid without the links to the confidential agents etc.

I hear the Clinical Tx WG is interested in reviewing and providing edits/additions. If the ACTIV-4/NHLBI reps on the WG would like to make changes they should work closely with Amy Patterson – the current info provided was vetted by Amy and her team.

Once the WG group has collective edits we will update those on the live version. Please let us know if this plan works for FNIH—cc'ing Stacey as well.

Thanks,
Ashley

<DRAFT NIH_ACTIV Checkerboard_8.29.2020.pptx>

<Checkerboard for ACTIV and NIH COVID Trials 08.29.2020.xlsx>

<Copy of Planned COVID-19 clinical studies master_2020.08.11_AP0813_LB0829.xlsx>

From: George, Jill (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F90BFFB4B3A2464382ADC29B127AED4E-GEORGEJIL]
Sent: 8/20/2020 7:45:31 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Link to ACTIV 2 study web page

Thanks!

Now back to your vacation... 😊

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 20, 2020 3:32 PM
To: George, Jill (NIH/OD) [E] [b6]
Subject: Fwd: Link to ACTIV 2 study web page

FYI — [CT.gov](https://www.ct.gov) links for the grid for ACTIV 2 and ACTIV 3.

I haven't seen any responses from FC since our latest version was sent last Friday!

Ashley Parker, Ph.D.

Office of the Director | National Institutes of Health

Tel: [b6]

Begin forwarded message:

From: "Wojtowicz, Emma (NIH/OD) [E]" [b6]
Date: August 20, 2020 at 12:11:56 PM EDT
To: "Brodd, Lauren (NIH/OD) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Myles, Renate (NIH/OD) [E]" [b6]
Subject: RE: Link to ACTIV 2 study web page

Thanks! We will add the links.

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Thursday, August 20, 2020 12:11 PM
To: Parker, Ashley (NIH/OD) [E] [b6] Myles, Renate (NIH/OD) [E] [b6]
Cc: Wojtowicz, Emma (NIH/OD) [E] [b6]
Subject: RE: Link to ACTIV 2 study web page

Hi Renate and Emma,

I noticed that as of this morning, ACTIV-2 and ACTIV-3 are now both up on [CT.gov](https://www.ct.gov):

ACTIV-2 [NCT04518410](https://www.clinicaltrials.gov/ct2/show/study/NCT04518410)

ACTIV-3 [NCT04501978](https://www.clinicaltrials.gov/ct2/show/study/NCT04501978)

Just wanted to share in case you hadn't seen it since you had mentioned the links will be included on the website.

APAR0000002343

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 5, 2020 7:56 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: Re: Link to ACTIV 2 study web page

I was looking for the ACTIV 2-3 trials on [CT.gov](https://www.ct.gov) yesterday. Hopefully they will post soon.

Thanks,
Ashley

On Aug 5, 2020, at 7:53 AM, Myles, Renate (NIH/OD) [E] [b6] wrote:

Thanks. We can link to it. We are planning to link to [CT.gov](https://www.ct.gov) as soon as the records have been established.

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
[b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 5, 2020 7:51:35 AM
To: Myles, Renate (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E]
[b6]
Subject: Fwd: Link to ACTIV 2 study web page

FYI

Begin forwarded message:

From: "Menetski, Joseph (FNIH) [T]" [b6]
Date: August 5, 2020 at 7:38:50 AM EDT
To: "Wholley, David (FNIH) [T]" [b6] "Collins, Francis (NIH/OD) [E]" [b6], "Tabak, Lawrence (NIH/OD) [E]" [b6], "Austin, Christopher (NIH/NCATS) [E]" [b6], "Lane, Cliff (NIH/NIAID) [E]" [b6], "Parker, Ashley (NIH/OD) [E]" [b6], "Anderson, James (NIH/OD) [E]" [b6], "Freire, Maria (FNIH) [T]" [b6]
Subject: Link to ACTIV 2 study web page

Dear All,

Stacey forwarded this to me and we thought you would be interested to see it. It is very cool!

<https://www.activ-2.org/>

Joe

From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 8/5/2020 11:57:22 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Link to ACTIV 2 study web page

I was also looking yesterday, so yes hopefully they post soon!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 5, 2020 7:56 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Cc: Brodd, Lauren (NIH/OD) [E]
Subject: Re: Link to ACTIV 2 study web page

I was looking for the ACTIV 2-3 trials on [CT.gov](https://www.ct.gov) yesterday. Hopefully they will post soon.

Thanks,
Ashley

On Aug 5, 2020, at 7:53 AM, Myles, Renate (NIH/OD) [E] [b6] wrote:

Thanks. We can link to it. We are planning to link to [CT.gov](https://www.ct.gov) as soon as the records have been established.

Renate Myles
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
[b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 5, 2020 7:51:35 AM
To: Myles, Renate (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E]
[b6]
Subject: Fwd: Link to ACTIV 2 study web page

FYI

Begin forwarded message:

From: "Menetski, Joseph (FNIH) [T]" [b6]
Date: August 5, 2020 at 7:38:50 AM EDT
To: "Wholley, David (FNIH) [T]" [b6] "Collins, Francis (NIH/OD) [E]"
[b6], "Tabak, Lawrence (NIH/OD) [E]" [b6]
"Austin, Christopher (NIH/NCATS) [E]" [b6], "Lane, Cliff (NIH/NIAID)
[E]" [b6] "Parker, Ashley (NIH/OD) [E]" [b6]
"Anderson, James (NIH/OD) [E]" [b6], "Freire, Maria (FNIH) [T]"

b6

Subject: Link to ACTIV 2 study web page

Dear All,

Stacey forwarded this to me and we thought you would be interested to see it. It is very cool!

<https://www.activ-2.org/>

Joe

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 6/30/2020 4:00:50 PM
To: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Billet, Courtney (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7605eeb349ac41138b32fe3978e3986d-billetc]; Stover, Kathy (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82722674ba14c2f969bd50dfa6a7af4-stoverk]; Routh, Jennifer (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3b5bba3619344e38037ca94a71473a8-routhj]; Johnson, Lenora (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=059e53e386aa42fea27c7e17a4cc3cd7-johnslen]; Viers, Hillary (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2e4fa79d544133a5609cbdb246f571-viershw]; Hochman, Lauren (NIH/NHLBI) [C] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b59d1b48825492d9e156be3135b0cda-hochmanlk]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Chen, Helen Q. [qingchen@deloitte.com]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]
CC: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Stimson, Daniel (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=800d5bd0d3854a75b9bf393f0c088a58-stimmond]
Subject: CLOSE HOLD: ACTIV Therapeutics Communication Discussion
Attachments: Upcoming COVID19 clinical trials 6.30.docx

See attached table on close hold.

-----Original Appointment-----

From: Myles, Renate (NIH/OD) [E]
Sent: Friday, June 26, 2020 10:50 AM
To: Myles, Renate (NIH/OD) [E]; John (NIH/OD) Burklow [E]; Fine, Amanda (NIH/OD) [E]; Wojtowicz, Emma (NIH/OD) [E]; Billet, Courtney (NIH/NIAID) [E]; Stover, Kathy (NIH/NIAID) [E]; Routh, Jennifer (NIH/NIAID) [E]; Johnson, Lenora (NIH/NHLBI) [E]; Viers, Hillary (NIH/NHLBI) [E]; Hochman, Lauren (NIH/NHLBI) [C]; Parker, Ashley (NIH/OD) [E]; Wholley, David (FNIH) [T]; Adam, Stacey (FNIH) [T]; Chen, Helen Q.; Meltzer, Abbey (FNIH) [T]; Gorman, Greta (FNIH) [T]
Cc: Brodd, Lauren (NIH/OD) [E]; Stimson, Daniel (NIH/NHLBI) [E]
Subject: ACTIV Therapeutics Communication Discussion
When: Tuesday, June 30, 2020 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Web Ex Details Below

Hi all:

Below is a draft agenda. Let me know if there are other items that you think we need to cover. Wanted to go ahead and send this to get it on everyone's calendars.

Draft Agenda:

- Current expected timing on ACTIV projects
- Project nomenclature
- NIAID/NHLBI process for announcing new trials as regulatory sponsors and working with collaborators
- Coordination with company participants through ACTIV

-- Do not delete or change any of the following text. --

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Dial @lync.webex.com

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From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 6/29/2020 9:28:20 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Moderna and Novavax

Thanks!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, June 29, 2020 5:23 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: FW: Moderna and Novavax

FYI – will follow up if someone opposes.

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, June 29, 2020 5:22 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Gorman, Greta (FNIH) [T] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Moderna and Novavax

I don't see an issue doing that but am asking my team in case there are any red flags I do not see.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, June 29, 2020 5:20 PM
To: Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Moderna and Novavax

Hi David and Cheryl,

I understand that Moderna and Novavax have members on the vaccines working group but are not members of the leadership team. Given we list all companies who represent the working groups on the NIH ACTIV <https://www.nih.gov/research-training/medical-research-initiatives/activ#organizations> and FNIH website <https://fnih.org/what-we-do/programs/activ-partnership>, I wanted to confirm that we should add their company names?

If this is OK – I will also suggest to our team and FNIH we change the current headings as “leadership organizations” to something like “ACTIV Partners”? Others who are not leadership i.e. BMGF are listed under this umbrella and I understand we want to be clear to note the difference.

Thank you,
Ashley

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 6/30/2020 1:30:27 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]
Subject: RE: Moderna and Novavax

I'd say 18 to be conservative. You'd want to be able to have the press call Moderna and have them say, oh yes we are an ACTIV partner, we go to all the meetings. Whereas I am not sure they look at themselves that way—more of an NIAID/OWS partner in terms of their interactions so far.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, June 29, 2020 9:24 PM
To: Wholley, David (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]
Subject: Re: Moderna and Novavax

Hi David,

To complicate things a bit or at least come to a decision — Dr. Collins has a Senate appropriations hearing on Thursday and we have the number of industry partners for ACTIV written in his oral testimony. We currently state there are 18 industry partners — do we want to include Moderna and Novavax and say there are now 20?

If not, we will leave as 18.

Thank you,
Ashley

On Jun 29, 2020, at 6:17 PM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

APAR0000002571

Great points. The latter would be the easiest solution but defer to David's preference on adding to the leadership team — I don't think this was preferred previously. Any non-profits not on the leadership team would also need to be removed.

If we move forward with listing "all partners", yes we would need to update the sites and include academics as well.

Thank you,
Ashley

On Jun 29, 2020, at 5:32 PM, Santos, Michael (FNIH) [T] [b6] wrote:

That approach is fine with me, though if we go that route do you plan to add the affiliations of other Working Group members under the "Non-profit" heading? E.g., in the Vaccines WG, we have some other organizations (e.g., Stanford, U of Washington, UCSF, Duke, Baylor, Penn) represented that do not have Leadership Team members.

Alternatively, if we want to either leave things as-is or invite additional companies to the Leadership Team, I think those would also be reasonable solutions.

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, June 29, 2020 5:22 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Cc: Gorman, Greta (FNIH) [T] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Moderna and Novavax

I don't see an issue doing that but am asking my team in case there are any red flags I do not see.

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Subject: Moderna and Novavax

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I understand that Moderna and Novavax have members on the vaccines working group but are not members of the leadership team. Given we list all companies who represent the working groups on the NIH ACTIV <https://www.nih.gov/research-training/medical-research-initiatives/activ#organizations> and FNIH website <https://fnih.org/what-we->

do/programs/activ-partnership, I wanted to confirm that we should add their company names?

If this is OK – I will also suggest to our team and FNIH we change the current headings as “leadership organizations” to something like “ACTIV Partners”? Others who are not leadership i.e. BMGF are listed under this umbrella and I understand we want to be clear to note the difference.

Thank you,
Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 3/3/2021 3:48:44 PM
To: Appell, Evan [eappell@deloitte.com]
Subject: RE: ACTIV & NIH Data Sharing and Collaboration

Hi Evan,

I created my basecamp account, can you please grant permission to access the "ACTIV / NIH Data Sharing & Collaboration."

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, February 26, 2021 11:52 PM
To: Appell, Evan <eappell@deloitte.com>
Subject: RE: ACTIV & NIH Data Sharing and Collaboration

Thanks! I will let you know once I create an account on Monday.

From: Appell, Evan <eappell@deloitte.com>
Sent: Friday, February 26, 2021 5:57 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV & NIH Data Sharing and Collaboration

Hi Ashley,

Just let me know when you've created your Basecamp account and then I'll be sure to add you to the site. Hope you have a nice weekend!

Thanks,
Evan

Evan Appell
Deloitte Consulting LLP
Mobile [b6]
eappell@deloitte.com

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, February 26, 2021 5:07 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Appell, Evan <eappell@deloitte.com>; Adam, Stacey (FNIH) [T] [b6]
Subject: [EXT] RE: ACTIV & NIH Data Sharing and Collaboration

Thanks, David!

Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, February 26, 2021 3:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]

Subject: FW: ACTIV & NIH Data Sharing and Collaboration

Hi Ashley:

As have heard on war room earlier this week, we had a request from Yves Rosenberg to access information on the agents prioritized by the ACTIV Therapeutics Working Group in order to inform prioritization discussions at NHLBI. In response the ACTIV FNIH/Deloitte team has created a shared site on a platform called Basecamp which can be used to share information between our groups on which agents have been reviewed as potential treatments / therapeutics for COVID-19. The site includes summaries of the results of the deliberations of the ACTIV Agent Prioritization Workgroup on those agents that went beyond the initial triage stage, anonymized to remove the reviewer names. Given your role and the kinds of queries about the prioritization process you get, I thought you could use access to this.

Below please find an overview of how to access the Basecamp site, along with details on the materials that have already been uploaded.

As you know, we are also granting access to specified individuals within the major ICs involved in ACTIV: NIAID, NHLBI, NINDS, and NCATS.

Please let me and Evan Appell of Deloitte Consulting know if you have any questions or difficulty accessing the site, and our team can help to troubleshoot as needed. Thanks,

David

Accessing Basecamp:

1. In order to access Basecamp, the individual must **create an account** on Basecamp (*only if you do not have a Basecamp account already)
 - o This can easily be done by following this link:
https://3.basecamp.com/signup/account/new?plan=one_v1
2. Once the individual has created their account, they should inform the ACTIV team so that we can **grant them permission** to access the “**ACTIV / NIH Data Sharing & Collaboration**” Basecamp site
 - o The individual will then receive an email **directly from Basecamp** (not from FNIH) alerting them that they have been given access to the “**ACTIV / NIH Data Sharing & Collaboration**” Basecamp site
3. Once the individual has been granted permission to the site, they can **access it through the email that was sent to them or by following this link:** <https://3.basecamp.com/3948057/projects/21021910>

Materials Available on the Basecamp site:

4. Once an individual enters the “**ACTIV / NIH Data Sharing & Collaboration**” Basecamp site, they will see a “**Docs & Files**” folder which contains a **PowerPoint file** titled “*ACTIV_TX-Preclinical and Clinical_Agent Prioritization Summary_vSHARE*”
 - o They can then download this file from Basecamp, and view it on their desktop app
5. The file includes a **summary of all agents that have been reviewed** by the ACTIV Therapeutics-Clinical Agent Prioritization Sub Teams.
A few brief notes on what is included in this file:
 - o There are ~200 reviews of Antiviral, Immune Modulator, and Symptomatic / Supportive agents that have been evaluated by ACTIV
 - o We have included a summary of the scoring criteria that were used to assess each agent at the very front of the deck
 - o There is a table of contents in the beginning of the deck listing all of the agents that have been reviewed (which also includes hyperlinks that can be used to navigate directly to the detailed review of any particular agent)

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/31/2020 9:57:23 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Sites and Locations for ACTIV-2

Thanks, Stacey. No worries, I will standby for the PPD sites – I am waiting for others as well.

Thanks again for your help with this.
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, August 31, 2020 5:53 PM
To: Parker, Ashley (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6]
Subject: RE: Sites and Locations for ACTIV-2

Thanks, Ashley,

The ACTG team was very forthcoming, but PPD is taking longer.

Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, August 31, 2020 5:52 PM
To: Adam, Stacey (FNIH) [T] [b6] Wholley, David (FNIH) [T] [b6]
Subject: RE: Sites and Locations for ACTIV-2

Hi Stacey,

For right now we are gathering the locations of the NIH and ACTIV trials to compare them with the locations where HRSA has mobile units and may be able to assist.

I can standby for the more complete list – we will send this to HRSA for the comparison.

Thanks very much.
Ashley

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, August 31, 2020 5:42 PM
To: Parker, Ashley (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6]
Subject: RE: Sites and Locations for ACTIV-2

Hi Ashley,

Attached are all the "potential" domestic sites from the ACTG network for ACTIV-2 in your template. The team is still working through which order these will be activated in, and this list does not include the sites that PPD will recruit and contract with directly. I am still waiting on those, but I wanted to get you something.

Question, as the team does not know yet which of these will rise to priority fastest. How are you using this information?

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Monday, August 31, 2020 1:25 PM

To: Adam, Stacey (FNIH) [T] [b6] Wholley, David (FNIH) [T] [b6]

Subject: Sites and Locations for ACTIV-2

Hi Stacey and David,

We are working to get additional assistance with space/mobile units for the ACTIV outpatient trials. In an effort to match locations of the mobile units we need the list of institutional sites and locations for ACTIV-2.

Attached is a template, Stacey do you have the contacts that can help provide us with the list? Would they be able to gather this information by COB today?

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/24/2020 6:37:46 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Got it – thanks David and Joe!

Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Monday, August 24, 2020 8:33 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Menetski, Joseph (FNIH) [T] <jmenetski@fnih.org>; Adam, Stacey (FNIH) [T] <sadam@fnih.org>; Santos, Michael (FNIH) [T] <msantos@fnih.org>
Subject: FW: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Ashley: Another county heard from.

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Monday, August 24, 2020 7:53 AM
To: Wholley, David (FNIH) [T] [b6] Adam, Stacey (FNIH) [T] [b6] Santos, Michael (FNIH) [T] [b6]
Cc: Tountas, Karen (FNIH) [T] [b6]
Subject: RE: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

David,
Under hospitalized non-ventilator and mAb there is a n entry for tocilizumab, with is a mAb, but should be in immunomodulator since it is directed at IL-6.

I think the mAb should be neutralizing Ab, and tocilizumab should be in immunomodulators. It is not consistent the way it is because there are other mAb in immunomodulators (which they are).

Joe

From: Wholley, David (FNIH) [T] [b6]
Sent: Sunday, August 23, 2020 3:02 PM
To: Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]
Cc: Menetski, Joseph (FNIH) [T] [b6] Tountas, Karen (FNIH) [T] [b6]
Subject: FW: COVID-19 Planned Clinical Activities -CONFIDENTIAL DO NOT DISTRIBUTE

Hi all – the attached grid has been in discussion for several weeks as an antidote to public confusion about what is ACTIV and what it is not (e.g. “ACTIV-Affiliated Studies” and Other NIH Efforts, to put it broadly). Can you please have a look and tell me if anything seems mis-categorized to you or if there is anything missing? Please do not copy or distribute. Thanks, David

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Sunday, August 23, 2020 1:48 PM
To: Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]
Subject: FW: COVID-19 Planned Clinical Activities

Hi all,

As you can see in the attachment, Ashley has added additional NIH-funded trials to the checkerboard matrix that was suggested by Maria a couple of weeks ago. See attached. Let's discuss where we might want to take this at tomorrow's War Room call.

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, August 14, 2020 6:41 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities

Hi Francis,

Attached is an update on the NIH, ACTIV, and ACTIV-like clinical trials. We've added many NIH funded trials that were submitted to the trans-NIH planned trials spreadsheet. We can continue to make revisions once we know what information (agent, trial phase, trial sponsor or NIH funded IC etc.) is preferred for the hover over and we've provided links to CT.gov for additional trial details if available.

I've given Renate a heads up that there is interest to make this public facing on the ACTIV website with the understanding that we will not post any trials until they have launched.

As you know I am on annual leave next week, however Jill cc'd is prepared to make additional revisions as needed for preferred info, colors, etc.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, August 14, 2020 12:05 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities

Hi Francis,

There are trials in the attached spreadsheet that could fill some blanks on the CT grid. Please see below:

- Line 44 mAbs for prophylaxis
- Line 35 RTB101 antiviral prophylaxis and early outpatient
- Line 59 IVIG + remdesivir in outpatients/early symptoms
- Line 15 other therapies for outpatients/early symptoms
- Line 13 and 18 other therapies for hospitalized
- Line 23 mAb for hospitalized (ACTIV 3 is all combo therapy mAb + remdesivir)

There are several others that could be included in spaces where we already have ACTIV trials. If we want to add these we will need to decide what features (name of compounds, trial phase, NCT link) should be included in the "hover over" and link to CT.gov for additional details.

Jill and I are in the process of making updates and should have an updated grid to share tomorrow.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 13, 2020 4:10 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: FW: COVID-19 Planned Clinical Activities

Hi Ashley,

Can you look at this and consider whether any of this information would be useful in filling in blanks in the clinical trial checkerboard?

FC

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Thursday, August 13, 2020 10:08 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Dickens, Jim (NIH/NCATS) [E] [b6]; Cutillo, Christine (NIH/NCATS) [E] [b6]
Kurilla, Michael (NIH/NCATS) [E] [b6]
Subject: COVID-19 Planned Clinical Activities

Francis and Larry,

In response to our need to know what COVID clinical trials the ICOs are planning so they can be coordinated with ACTIV activities, a few weeks ago I sent out a data call seeking information on all planned COVID-19 clinical research activities, which **are not** available in publicly accessible databases. This complements the Clinical Trial Tracker I sent the email about last night, which is derived from publicly accessible databases (ct.gov, WHO). I've attached the original data call which outlines details of the data call. The NCATS team has pulled together all the submissions from across the ICs for your use. The first tab of the spreadsheet is a summary of which ICs did and did not submit information and how many proposed research activities/multisite trials are likely to be funded per IC. Trial details are on the second tab. We did not get a 100% response rate from the ICs and therefore there may be some trials that are not included here. You'll see that 112 planned studies were reported, across a wide variety of observational and interventional trials.

This information will be very useful for ACTIV, but is sensitive nonpublic information so not widely shareable. I would be glad to send to others you think need this information, and even to FNIH if you think we could legally do so under a CDA.

Special thanks go to Jim Dickens who did the heavy lifting on this.

Please let me know if you have any questions.

Chris

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/25/2020 6:13:14 PM
To: Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
Subject: FW: ACTIV2 Central IRB Waiver Version 2
Attachments: ACTIV2 Central IRB Waiver_082520.pdf

FYI

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, August 25, 2020 2:05 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
McManus, Ayanna (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6] Adam,
Stacey (FNIH) [T] [b6]
Subject: RE: ACTIV2 Central IRB Waiver Version 2

Here you go.

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, August 25, 2020 12:05 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
McManus, Ayanna (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6] Adam,
Stacey (FNIH) [T] [b6]
Subject: FW: ACTIV2 Central IRB Waiver Version 2

Hi Francis:

Regarding the local IRB waiver letter for ACTIV-2: As I mentioned on the daily active call this morning we have incorporated Carrie Wolinetz's suggestions and were just checking as a courtesy with Mike Lauer to see if there were folks other than the IRB Chairs we should send this to, but it has been over a day and Mike we know is very busy with other things. We think the network leads will know where to take this, and meanwhile are getting pressure from OWS and ACTIV-2 reps to move this forward. Would it be possible therefore for you to sign this and return it to me today? Please copy Stacey Adam on the reply. Thanks, David

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/14/2020 3:18:43 AM
To: Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]
Subject: RE: CP RCT Meeting Summary -- and urgent timeline

Sounds good – have a good night.
Ashley

From: Patterson, Amy (NIH/NHLBI) [E] [b6]
Sent: Thursday, August 13, 2020 11:17 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: CP RCT Meeting Summary -- and urgent timeline

Hi Ashley, will take a close look at this in the AM when my brain cell are all firing ! We are familiar with REMAP CAP and have tried to harmonized some of the endpoints with them I know in a couple of our trials (e.g., ORCHID)

Sent from my iPhone

On Aug 13, 2020, at 10:25 PM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Hi Amy,

I am forwarding the note from Lise below from the REMAP-CAP CP study. She mentions harmonization with ACTIV-4 and suggest the same could be done for CP – sending as FYI in case this is something NHLBI would like to pursue. However, I do not plan to do anything further unless you suggest otherwise.

FC doubts much could be done in 6 weeks with UK sites but I wanted to share.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 13, 2020 10:14 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: CP RCT Meeting Summary -- and urgent timeline

Fine to forward to Amy – but I doubt REMAP-CAP will be able to enroll enough patients in the next six weeks to add very much to the power.

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 13, 2020 5:37 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: CP RCT Meeting Summary -- and urgent timeline

Hi Francis,

I received the note from Lise Escourt, REMAP-CAP study below. Is there anything we could do to link UK sites with any of the CP trials? Lise references harmonization with ACTIV-4, should we connect Lise with Amy and C3PO's efforts for possible expansion or harmonization of protocols?

Thanks,
Ashley

From: Estcourt Lise <[REDACTED] b6 [REDACTED]>
Sent: Thursday, August 13, 2020 5:14 PM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6 [REDACTED]
Subject: Re: CP RCT Meeting Summary -- and urgent timeline

Dear Ashley,

Just to follow-up, is there anything more you would like to know about the REMAP-CAP trial

Thanks for letting me know

Lise

Dr Lise Estcourt

Consultant Haematologist

Clinical Lead for the National Comparative Audit in Blood Transfusion

Director of NHSBT Clinical Trials Unit

Clinical Tutor, NHSBT

NHS Blood and Transplant

Oxford

Mobile: [REDACTED] b6 [REDACTED]

Phone: [REDACTED] b6 [REDACTED]

Twitter: @NHSBT

PA Anna Welford [REDACTED] b6 [REDACTED]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: 30 July 2020 17:37
To: Estcourt Lise [b6]
Cc: McVerry, Bryan J [b6] Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: CP RCT Meeting Summary -- and urgent timeline

Dear Lise,

Received – thank you.

Ashley

From: Estcourt Lise [b6]
Sent: Thursday, July 30, 2020 11:58 AM
To: Collins, Francis (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Cc: McVerry, Bryan J [b6]
Subject: Re: CP RCT Meeting Summary -- and urgent timeline

Please find attached requested details of the REMAP-CAP trial,

In response to your questions:

- **If resources were unlimited, what could be done to accelerate enrollment?**

Provide ability to rapidly onboard sites to the REMAP-CAP trial. This would have synergy with other interventions as it is a platform-based trial.

REMAP-CAP has established a precedent for harmonization with an existing NIH Network (ACTIV-4) through the therapeutic anticoagulation domain. This could be done for convalescent plasma using the same infrastructure.

- **What barriers would need to be overcome?**

FDA approval to administer CP as an investigational therapy as opposed to under the extended access IND we are currently operating under. Accelerated approval to do so will allow for rapid recruitment as sites get added to the REMAP-CAP Network in the U.S.

- **How many participants could be enrolled by August 31? By September 30?**

At UPMC could randomise up to 90 participants per month. With additional sites – up to 21 additional sites in contract discussion could increase the number of participants randomised significantly in to 100s per month.

- **When would a read-out of the study be possible?**

Depends on funding and recruitment of sites. Our trial has an adaptive design with the ability to favour randomisation to the intervention showing more benefit. It also allows the ability to

perform multiple interim analyses and stop when there is sufficient evidence. Statistics being performed by Scott Berry

- What would that cost?

Activation of a CP domain at sites with existing infrastructure will reduce the cost of enrollment per patient. As an additional domain with an established core protocol we estimate approximately \$5K per patient. This is much less than a stand-alone trial as it is likely to cost more in the neighbourhood of \$10-15K per patient with additional start-up costs for each site (~\$10K).

please let me know if you would like to know anything further

Kind regards

Lise

Dr Lise Estcourt

Consultant Haematologist

Clinical Lead for the National Comparative Audit in Blood Transfusion

Director of NHSBT Clinical Trials Unit

Clinical Tutor, NHSBT

NHS Blood and Transplant

Oxford

Mobile:

Phone:

b6

Twitter: @NHSBT

PA Anna Welford

b6

From: Collins, Francis (NIH/OD) [E] <b6>
Sent: 29 July 2020 18:54
To: Tabak, Lawrence (NIH/OD) [E] <b6> Anderson, James (NIH/OD) [E]
<b6>; Lauer, Michael (NIH/OD) [E] <b6>; Austin,
Christopher (NIH/NCATS) [E] <b6>; Lane, Cliff (NIH/NIAID) [E] <b6>;
Fauci, Anthony (NIH/NIAID) [E] <b6>; Gibbons, Gary (NIH/NHLBI) [E]
<b6>; Patterson, Amy (NIH/NHLBI) [E] <b6>; Rutter, Joni
(NIH/NCATS) [E] <b6>; Kurilla, Michael (NIH/NCATS) [E] <b6>;
Woodcock, Janet (FDA/CDER) <b6>; Disbrow, Gary (OS/ASPR/BARDA)
<b6>; Freire, Maria (FNIH) [T] <b6>; Wholley, David (FNIH) [T]
<b6>; Marks, Peter (FDA/CBER) <b6>; Hoots, W. Keith
(NIH/NHLBI) [E] <b6>; Glynn, Simone (NIH/NHLBI) [E] <b6>;
Groesch, Mary (NIH/NHLBI) [E] <b6>; Shipp, Allan (NIH/NHLBI) [E]
<b6>; Punturieri, Antonello (NIH/NHLBI) [E] <b6>

b6

<b6>; Ralph Sacco <b6>; Jayaweera, Dushyantha (NIH)

b6

<b6>; Santos, Michael (FNIH) [T] <b6>
<b6> Estcourt Lise <b6>

Roberts David <b6>;
Homer, Mary (OS/ASPR/BARDA) <b6>

b6

Cc: Parker, Ashley (NIH/OD) [E] <b6>; Collins, Francis (NIH/OD) [E]

<b6>

Subject: CP RCT Meeting Summary -- and urgent timeline

Dear Colleagues,

I greatly appreciate everyone who was available to join the convalescent plasma RCT discussion yesterday on such short notice. As promised, attached is the meeting summary. I am asking the principal investigators from each of the RCTs to send responses to the questions outlined below to Dr. Ashley Parker, <b6> cc'ing me **by noon tomorrow, July 30.**

Here is what I'm looking for:

Many of you have already provided clinical trial information in the attached excel spreadsheet, many thanks.

Thank you,
Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/12/2020 6:55:42 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
Subject: RE: ACTIV Daily Update 20200812.pptx

Thanks, David. I will continue with the ACTIV and ACTIV associated trials i.e. IVIG and CP – expanding to all NIH COVID trials sounds like role for the trans-NIH Clinical Trial WG #2.

Thanks again,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 2:29 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Freire, Maria (FNIH) [T] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Well, we have not decided exactly, but I thought we were entertaining ACTIV for trials 1-4 and probably 5 (BET), “ACTIV-Associated Trials” for IVIG and Conv. Plasma efforts, and NIH Covid Trials for everything else.h

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 2:17 PM
To: Wholley, David (FNIH) [T] [b6]
Cc: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Hi David,

Sorry I missed this. What did we decide? ACTIV and NIH COVID Treatment Trials? ACTIV and ACTIV-Like Trials?

I will rename the BET trial as (ACTIV-5), include the IVIG (ACTIV-like 6 or ACTIV-6 study?), and rename the CP trials (ACTIV-like 7a; 7b; etc.?)

Thank you,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 8:55 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Anderson, James (NIH/OD)

[E] { b6 }

Subject: RE: ACTIV Daily Update 20200812.pptx

I think you'd need to change the title from "ACTIV" on the first slide as we discussed, and a key to explain the colors would be good, but agree with Jim this is a great summary.

From: Parker, Ashley (NIH/OD) [E] { b6 }

Sent: Wednesday, August 12, 2020 8:28 AM

To: Wholley, David (FNIH) [T] { b6 } >; Collins, Francis (NIH/OD) [E] { b6 } >; Tabak, Lawrence (NIH/OD) [E] { b6 } >; Lane, Cliff (NIH/NIAID) [E] { b6 } >; Freire, Maria (FNIH) [T] { b6 } >; Austin, Christopher (NIH/NCATS) [E] { b6 } >; Anderson, James (NIH/OD) [E] { b6 } >

Subject: RE: ACTIV Daily Update 20200812.pptx

Please see the attached working draft of the ACTIV grid.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] { b6 }

Sent: Wednesday, August 12, 2020 7:17 AM

To: Collins, Francis (NIH/OD) [E] { b6 } >; Tabak, Lawrence (NIH/OD) [E] { b6 } >; Lane, Cliff (NIH/NIAID) [E] { b6 } >; Freire, Maria (FNIH) [T] { b6 } >; Austin, Christopher (NIH/NCATS) [E] { b6 } >; Parker, Ashley (NIH/OD) [E] { b6 } >; Anderson, James (NIH/OD) [E] { b6 } >

Subject: ACTIV Daily Update 20200812.pptx

For this morning's war room, Wednesday August 12. N.B. Maria may not be able to join.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/24/2020 12:31:07 PM
To: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]
Subject: RE: COVID-19 Planned Clinical Activities

This was not the correct file so I decided not to share.

From: George, Jill (NIH/OD) [E] [b6]
Sent: Monday, August 24, 2020 7:40 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities

What do you think?
Please make sure I drew from your corrected file.
Thanks!

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Sunday, August 23, 2020 3:02 PM
To: Parker, Ashley (NIH/OD) [E] [b6] >; George, Jill (NIH/OD) [E] [b6]
Subject: FW: COVID-19 Planned Clinical Activities

FYI

From: Freire, Maria (FNIH) [T] [b6]
Sent: Sunday, August 23, 2020 2:35 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: COVID-19 Planned Clinical Activities

I know. And I wish there was less drama.

On the chart: I wonder if it would be helpful to have a companion table, with the exact same content but color-coded differently so that all the ACTIVs are in one color, the ACTIV-like in a different hue and the NIH trials in a third color. That would allow us to see the ACTIV portfolio immediately.

To take the visuals further, ACTIV could be blue, NIH yellow and ACTIV-like green (combination of blue and yellow) or red, blue and purple. OK, I am getting carried away...

On Aug 23, 2020, at 2:20 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Yes, it's CP. I wish it were a better story....

From: Freire, Maria (FNIH) [T] [b6]
Sent: Sunday, August 23, 2020 2:18 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: COVID-19 Planned Clinical Activities

Thanks Francis. I hear there will be an announcement today from the WH in a therapeutic agent. I imagine it is CP, for which you must have talking points. We shall see how all this goes. M.

On Aug 23, 2020, at 1:49 PM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi all,

As you can see in the attachment, Ashley has added additional NIH-funded trials to the checkerboard matrix that was suggested by Maria a couple of weeks ago. See attached. Let's discuss where we might want to take this at tomorrow's War Room call.

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, August 14, 2020 6:41 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities

Hi Francis,

Attached is an update on the NIH, ACTIV, and ACTIV-like clinical trials. We've added many NIH funded trials that were submitted to the trans-NIH planned trials spreadsheet. We can continue to make revisions once we know what information (agent, trial phase, trial sponsor or NIH funded IC etc.) is preferred for the hover over and we've provided links to CT.gov for additional trial details if available.

I've given Renate a heads up that there is interest to make this public facing on the ACTIV website with the understanding that we will not post any trials until they have launched.

As you know I am on annual leave next week, however Jill cc'd is prepared to make additional revisions as needed for preferred info, colors, etc.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, August 14, 2020 12:05 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: COVID-19 Planned Clinical Activities

Hi Francis,

There are trials in the attached spreadsheet that could fill some blanks on the CT grid. Please see below:

- Line 44 mAbs for prophylaxis
- Line 35 RTB101 antiviral prophylaxis and early outpatient
- Line 59 IVIG + remdesivir in outpatients/early symptoms
- Line 15 other therapies for outpatients/early symptoms
- Line 13 and 18 other therapies for hospitalized
- Line 23 mAb for hospitalized (ACTIV 3 is all combo therapy mAb + remdesivir)

There are several others that could be included in spaces where we already have ACTIV trials. If we want to add these we will need to decide what features (name of compounds, trial phase, NCT link) should be included in the "hover over" and link to CT.gov for additional details.

Jill and I are in the process of making updates and should have an updated grid to share tomorrow.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 13, 2020 4:10 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: FW: COVID-19 Planned Clinical Activities

Hi Ashley,

Can you look at this and consider whether any of this information would be useful in filling in blanks in the clinical trial checkerboard?

FC

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Thursday, August 13, 2020 10:08 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Dickens, Jim (NIH/NCATS) [C] [b6]; Cutillo, Christine (NIH/NCATS) [E] [b6]
Kurilla, Michael (NIH/NCATS) [E] [b6]
Subject: COVID-19 Planned Clinical Activities

Francis and Larry,

In response to our need to know what COVID clinical trials the ICOs are planning so they can be coordinated with ACTIV activities, a few weeks ago I sent out a data call seeking information on all planned COVID-19 clinical research activities, which **are not** available in publicly accessible databases. This complements the Clinical Trial Tracker I sent the email about last night, which **is** derived from publicly accessible databases (ct.gov, WHO). I've attached the original data call which outlines details of the data call. The NCATS team has pulled together all the submissions from across the ICs for your use. The first tab of the spreadsheet is a summary of which ICs did and did not submit information and how many proposed research activities/multisite trials are likely to be funded per IC. Trial details are on the second tab. We did not get a 100% response rate from the ICs and therefore there may be some trials that are not included here. You'll see that 112 planned studies were reported, across a wide variety of observational and interventional trials.

This information will be very useful for ACTIV, but is sensitive nonpublic information so not widely shareable. I would be glad to send to others you think need this information, and even to FNIH if you think we could legally do so under a CDA.

Special thanks go to Jim Dickens who did the heavy lifting on this.

Please let me know if you have any questions.

Chris
<DRAFT NIH_ACTIV Checkerboard_8.14.20 630PM.pptx>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/14/2020 2:17:28 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: CP RCT Meeting Summary -- and urgent timeline

OK – thanks.
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, August 13, 2020 10:14 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: CP RCT Meeting Summary -- and urgent timeline

Fine to forward to Amy – but I doubt REMAP-CAP will be able to enroll enough patients in the next six weeks to add very much to the power.

FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 13, 2020 5:37 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: CP RCT Meeting Summary -- and urgent timeline

Hi Francis,

I received the note from Lise Escourt, REMAP-CAP study below. Is there anything we could do to link UK sites with any of the CP trials? Lise references harmonization with ACTIV-4, should we connect Lise with Amy and C3PO's efforts for possible expansion or harmonization of protocols?

Thanks,
Ashley

From: Estcourt Lise <[b6]>
Sent: Thursday, August 13, 2020 5:14 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: CP RCT Meeting Summary -- and urgent timeline

Dear Ashley,

Just to follow-up, is there anything more you would like to know about the REMAP-CAP trial

Thanks for letting me know

Lise

Dr Lise Estcourt

Consultant Haematologist

Clinical Lead for the National Comparative Audit in Blood Transfusion

Director of NHSBT Clinical Trials Unit

Clinical Tutor, NHSBT

NHS Blood and Transplant

Oxford

Mobile:

b6

Phone:

Twitter: @NHSBT

PA Anna Welford

b6

From: Parker, Ashley (NIH/OD) [E]

b6

Sent: 30 July 2020 17:37

To: Estcourt Lise

b6

Cc: McVerry, Bryan J

b6

Collins, Francis (NIH/OD) [E]

b6

Subject: RE: CP RCT Meeting Summary -- and urgent timeline

Dear Lise,

Received – thank you.

Ashley

From: Estcourt Lise

b6

Sent: Thursday, July 30, 2020 11:58 AM

To: Collins, Francis (NIH/OD) [E]

b6

Parker, Ashley (NIH/OD) [E]

b6

Cc: McVerry, Bryan J

b6

Subject: Re: CP RCT Meeting Summary -- and urgent timeline

Please find attached requested details of the REMAP-CAP trial,

In response to your questions:

- If resources were unlimited, what could be done to accelerate enrollment?

Provide ability to rapidly onboard sites to the REMAP-CAP trial. This would have synergy with other interventions as it is a platform-based trial.

REMAP-CAP has established a precedent for harmonization with an existing NIH Network (ACTIV-4) through the therapeutic anticoagulation domain. This could be done for convalescent plasma using the same infrastructure.

- **What barriers would need to be overcome?**

FDA approval to administer CP as an investigational therapy as opposed to under the extended access IND we are currently operating under. Accelerated approval to do so will allow for rapid recruitment as sites get added to the REMAP-CAP Network in the U.S.

- **How many participants could be enrolled by August 31? By September 30?**

At UPMC could randomise up to 90 participants per month. With additional sites – up to 21 additional sites in contract discussion could increase the number of participants randomised significantly in to 100s per month.

- **When would a read-out of the study be possible?**

Depends on funding and recruitment of sites. Our trial has an adaptive design with the ability to favour randomisation to the intervention showing more benefit. It also allows the ability to perform multiple interim analyses and stop when there is sufficient evidence. Statistics being performed by Scott Berry

- **What would that cost?**

Activation of a CP domain at sites with existing infrastructure will reduce the cost of enrollment per patient. As an additional domain with an established core protocol we estimate approximately \$5K per patient. This is much less than a stand-alone trial as it is likely to cost more in the neighbourhood of \$10-15K per patient with additional start-up costs for each site (~\$10K).

please let me know if you would like to know anything further

Kind regards

Lise

Dr Lise Estcourt

Consultant Haematologist

Clinical Lead for the National Comparative Audit in Blood Transfusion

Director of NHSBT Clinical Trials Unit

Clinical Tutor, NHSBT

NHS Blood and Transplant

Oxford

Mobile: **b6**
Phone: **b6**

Twitter: @NHSBT

PA Anna Welford **b6**

From: Collins, Francis (NIH/OD) [E] **b6**

Sent: 29 July 2020 18:54

To: Tabak, Lawrence (NIH/OD) [E] **b6**; Anderson, James (NIH/OD) [E]
b6; Lauer, Michael (NIH/OD) [E] **b6** Austin, Christopher (NIH/NCATS)
[E] **b6**; Lane, Cliff (NIH/NIAID) [E] **b6**; Fauci, Anthony (NIH/NIAID) [E]
b6; Gibbons, Gary (NIH/NHLBI) [E] **b6**; Patterson, Amy (NIH/NHLBI) [E]
b6; Rutter, Joni (NIH/NCATS) [E] **b6**; Kurilla, Michael (NIH/NCATS) [E]
Woodcock, Janet (FDA/CDER) **b6** Disbrow, Gary
(OS/ASPR/BARDA) **b6** Freire, Maria (FNIH) [T] **b6** Wholley, David (FNIH) [T]
b6; Marks, Peter (FDA/CBER) **b6** Hoots, W. Keith (NIH/NHLBI) [E]
b6; Glynn, Simone (NIH/NHLBI) [E] **b6** Groesch, Mary (NIH/NHLBI) [E]
Shipp, Allan (NIH/NHLBI) [E] **b6**; Punturieri, Antonello (NIH/NHLBI) [E]

b6

b6; Ralph Sacco **b6**; Jayaweera, Dushyantha
(NIH) **b6**

b6

b6; Santos, Michael
(FNIH) [T] **b6**; Estcourt Lise

b6; Roberts David **b6**
Homer, Mary (OS/ASPR/BARDA) **b6**
b6

Cc: Parker, Ashley (NIH/OD) [E] [b6] Collins, Francis (NIH/OD) [E] [b6]
Subject: CP RCT Meeting Summary -- and urgent timeline

Dear Colleagues,

I greatly appreciate everyone who was available to join the convalescent plasma RCT discussion yesterday on such short notice. As promised, attached is the meeting summary. I am asking the principal investigators from each of the RCTs to send responses to the questions outlined below to Dr. Ashley Parker, [b6] cc'ing me **by noon tomorrow, July 30**.

Here is what I'm looking for:

Many of you have already provided clinical trial information in the attached excel spreadsheet, many thanks.

Thank you,
Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/13/2020 12:56:41 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Elsaid, Olivia [oelsaid@deloitte.com]
Subject: RE: ACTIV EC Pre-call

Good morning David and Olivia,

We will share the attendee, agenda, and milestones slide for Dr. Collins' meeting with the Secretary – I just wanted to confirm that we have no additional changes on those slides.

Thank you,
 Ashley

Confidential and Pre-decisional

Attendees for ACTIV Executive Committee Meeting

ACTIV EXECUTIVE COMMITTEE		ACTIV WORKING GROUP CO-CHAIRS		NON-PROFIT
	Francis Collins*		Christine Colvis Mike Kurilla	 Maria Freire
	Paul Stoffels*		Sarah Read	
	Anthony Fauci		[Doug Lowy]	
	Gary Gibbons		Eric Hughes	
	Gary Diskrow		John Young	
	Janet Woodcock		Betsy Desrosiers	
	Peter Marks		[Kathrin Jensen]	
	William Pao			
	Mikael Dolsten			
	Andrew Plump			

PROGRAM MANAGEMENT

David Wholley
 Joe Menetski
 Stacey Adam
 Karen Tountas
 Michael Santos
 Stephanie James
 Margaret Anderson
 Nina Gonzalez
 Benjamin Stratton
 Olivia Elsaid
 Jonathan Wachtel
 Ross Alvarez
 Helen Chen
 Brett Tolman

 Notes: (i) Denotes a leader not able to attend; * Denotes ACTIV Executive Committee Co-Chair

2

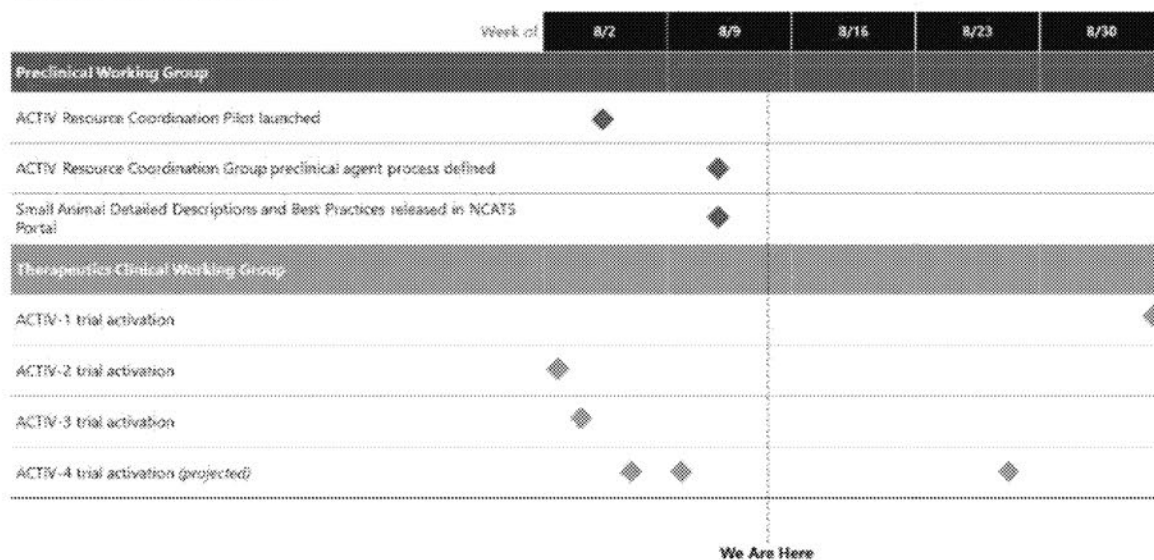
Agenda

TIME	TOPIC	SPEAKER(S)
12:00 – 12:05 PM 5 mins	Introduction and General Updates on ACTIV	Francis Collins (NIH) Paul Stoffels (J&J)
12:05 – 12:10 PM 5 mins	Progress on Action Items from Previous Meetings	David Wholley (FNIH)
12:10 – 12:30 PM 20 mins	Working Group Updates and Q&A	Christine Colvis (NCATS), John Young (Roche)
12:30 – 12:50 PM 20 mins		
	ACTIV Preclinical	
	ACTIV Therapeutics Clinical	
12:50 – 1:00 PM 10 mins	Milestones and Discussion	Francis Collins (NIH) David Wholley (FNIH)



Confidential and Pre-decisional

ACTIV Milestones



From: Wholley, David (FNIH) [T] [b6]

Sent: Wednesday, August 12, 2020 11:54 AM

To: Melencio, Cheryl (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Margaret <marganderson@deloitte.com>; Chen, Helen <qingchen@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; James, Stephanie (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Stratton, Benjamin <bstratton@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Hawk, Harrison <hhawk@deloitte.com>; Colvis, Christine (NIH/NCATS) [E] [b6]

Cc: Wood, Gretchen (NIH/OD) [E] [b6] McManus, Ayanna (NIH/OD) [E] [b6];
Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]
Subject: RE: ACTIV EC Pre-call
Importance: High

Please see attached the proposed slides and attendee list for our pre-call.

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6]

Sent: Tuesday, July 21, 2020 2:04 PM

To: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Benjamin; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Hawk, Harrison; Colvis, Christine (NIH/NCATS) [E]

Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

Subject: ACTIV EC Pre-call

When: Wednesday, August 12, 2020 12:00 PM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: see webex below

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/12/2020 5:23:15 PM
To: Austin, Christopher (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17597cab42247548e596778304f781f-austinc]; Schmitt, Clare (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4a12834fa5a4b8e972fd284d29f17b2-cschmitt]
CC: Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Dunsmore, Sarah (NIH/NIGMS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ead4a1420aa346cfbde4dace7bba42b5-dunsmores]; Boucher, Cynthia (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c1d80fc5e664e85ae8baf6833bc1734-boucherc]; Bozzette, Sam (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85f05a3619cf47c7ae39d7bcf0aac88d-bozzettesaa]; Atkinson, Jane (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0e3e449583b40e0b5bdfccfda71ced-jatkinso]
Subject: RE: ACTIV Daily Update 20200812.pptx

Will do and sounds good – thanks!

Ashley

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Wednesday, August 12, 2020 1:14 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Schmitt, Clare (NIH/NCATS) [E] [b6]
Cc: Kurilla, Michael (NIH/NCATS) [E] [b6]; Dunsmore, Sarah (NIH/NIGMS) [E] [b6]; Boucher, Cynthia (NIH/NCATS) [E] [b6]; Bozzette, Sam (NIH/NCATS) [E] [b6]; Atkinson, Jane (NIH/NCATS) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Hi Ashley,

A great deal has happened with ACTIV-1 in the last week and will be happening this week. Some of the information is not yet shareable (contract confidentiality). For this reason please remove DCRI as the sponsor. I have asked Jane and Clare for weekly progress reports on ACTIV1 and CP so Jane will have this for us by Friday and you can update then. All good I'm glad to say.

Chris

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, August 12, 2020 1:06 PM
To: Austin, Christopher (NIH/NCATS) [E] [b6]; Schmitt, Clare (NIH/NCATS) [E] [b6]
Cc: Kurilla, Michael (NIH/NCATS) [E] [b6]; Dunsmore, Sarah (NIH/NIGMS) [E] [b6]; Boucher, Cynthia (NIH/NCATS) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Hi Chris and Clare,

Thank you for the updates. Chris – while I am updating the CP trials, do we have updates on ACTIV -1? If not, I can use the information FNIH shared below.

Thanks,
Ashley

	ACTIV-1
NCT/CT.gov	
Trial Sponsor	DCRI
Collaborators	National Center for Advancing Translational Sciences (NCATS)
Therapy/Agents	Remdesivir, Infliximab (Remicade), Abatacept (Orencia), Cenicriviroc
Trial phase	phase 3
Enrollment Start date	8/30/2020
Estimated completion date	
Estimated early readout date	
Estimated enrollment	1,980
Actual enrollment	
Patient population	hospitalized adults
Brief Description	
Main inclusion criteria	
Main exclusion criteria	
Dose/route/regimen	IV and Oral
Primary Outcome Measures	Time to Recovery
Number of locations	
Countries	
Main PIs	William Powderly

From: Schmitt, Clare (NIH/NCATS) [E] [b6]
Sent: Wednesday, August 12, 2020 9:26 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Kurilla, Michael (NIH/NCATS) [E] [b6]; Austin, Christopher (NIH/NCATS) [E]
[b6] Schmitt, Clare (NIH/NCATS) [E] [b6]; Dunsmore, Sarah (NIH/NIGMS) [E]
[b6] Boucher, Cynthia (NIH/NCATS) [E] [b6]
Subject: RE: ACTIV Daily Update 20200812.pptx

Hi Ashley,

Below is the most recent information that I have on the expanded NYU-Einstein CT (up to 1000 patients) and the new Vanderbilt CT. We expect admin sup awards to be made to UT Houston, Miami, and Vanderbilt in the next 2 weeks (OWS funds).

APAR0000010783

08.10.2020 Update to OWS. YELLOW = value entered on OWS sheet

	NCT04364737					NCT04362176
Milestone	NYU-Einstein	Houston	Miami	COMBO		Vanderbilt
Enrollment target	220	400	360			1000
IND submission	Apr. 13, 2020*					Apr. 17, 2020; App'd Apr 22, 2020
First patient enrolled	Apr. 17, 2020	Aug. 17, 2020	Aug. 17, 2020			Apr. 28, 2020
50% patients enrolled	Jun. 8, 2020 (number reported for 6/8/2020 DSMB meeting)	Sep. 30, 2020	Sept. 16, 2020			Oct. 1, 2020
Enrollment closed	TBD	Dec. 31, 2020	Oct. 16, 2020			Oct. 31, 2020
Safety analysis	No issues last DSMB meeting					Sep. 11, 2020
Interim data analysis	Last Jul. 10, 2020 Next Aug. 28, 2020					Sep. 11, 2020
Final analysis	TBD					Nov. 30, 2020
# sites	7	4	2	13		≤50
Enrollment 08.07.2020	182	0	0	182		46**

***IND approval**

**** Represents enrollment from Vanderbilt, the only site enrolling during this period**

Take care,
Clare

Clare Schmitt, Ph.D.
Deputy Director, Division of Clinical Innovation
National Center for Advancing Translational Sciences
6701 Democracy Blvd, Office 932
Bethesda, MD 20892-4874
Phone: [b6]
E-mail: [b6]
NCATS Website: <http://ncats.nih.gov>

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Follow us on Twitter: https://twitter.com/ncats_nih_gov

From: Austin, Christopher (NIH/NCATS) [E] [b6]
Sent: Wednesday, August 12, 2020 8:40 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Kurilla, Michael (NIH/NCATS) [E] [b6]; Schmitt, Clare (NIH/NCATS) [E] [b6]
Subject: FW: ACTIV Daily Update 20200812.pptx

Hi Ashley,

There have been significant developments in both the CPLCCIHP (NYU) trial and another that is not on this grid, which is at Vanderbilt and harmonized with CPLCCIHP. Clare can get you this information.

These trials should be considered in the naming process we discussed yesterday and this morning on the WR. They were not planned through ACTIV but are receiving OWS as well as NCATS funding.

Thanks,

Chris

From: Parker, Ashley (NIH/OD) [E] <[b6]>
Sent: Wednesday, August 12, 2020 8:28 AM
To: Wholley, David (FNIH) [T] <[b6]>; Collins, Francis (NIH/OD) [E] <[b6]>; Tabak, Lawrence (NIH/OD) [E] <[b6]>; Lane, Cliff (NIH/NIAID) [E] <[b6]>; Freire, Maria (FNIH) [T] <[b6]>; Austin, Christopher (NIH/NCATS) [E] <[b6]>; Anderson, James (NIH/OD) [E] <[b6]>
Subject: RE: ACTIV Daily Update 20200812.pptx

Please see the attached working draft of the ACTIV grid.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Wednesday, August 12, 2020 7:17 AM
To: Collins, Francis (NIH/OD) [E] <[b6]>; Tabak, Lawrence (NIH/OD) [E] <[b6]>; Lane, Cliff (NIH/NIAID) [E] <[b6]>; Freire, Maria (FNIH) [T] <[b6]>; Austin, Christopher (NIH/NCATS) [E] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>; Anderson, James (NIH/OD) [E] <[b6]>
Subject: ACTIV Daily Update 20200812.pptx

For this morning's war room, Wednesday August 12. N.B. Maria may not be able to join.

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/13/2020 7:27:37 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Elsaid, Olivia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=userf0efa7bd]
Subject: RE: ACTIV EC Pre-call

OK. Sorry Olivia and David – the launch of these trials are a moving target and constantly changing.

David – I know the press briefings for ACTIV-4 is scheduled for 8/27 based on the note from Renate and we had this as the launch date for hospitalized patients, however since NHLBI has confirmed those dates, I guess it's safe to leave them. I did write a note to Amy to ask for confirmation given this is going to the Secretary.

Thanks so much,
Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, August 13, 2020 3:19 PM
To: Elsaid, Olivia <oelsaid@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV EC Pre-call

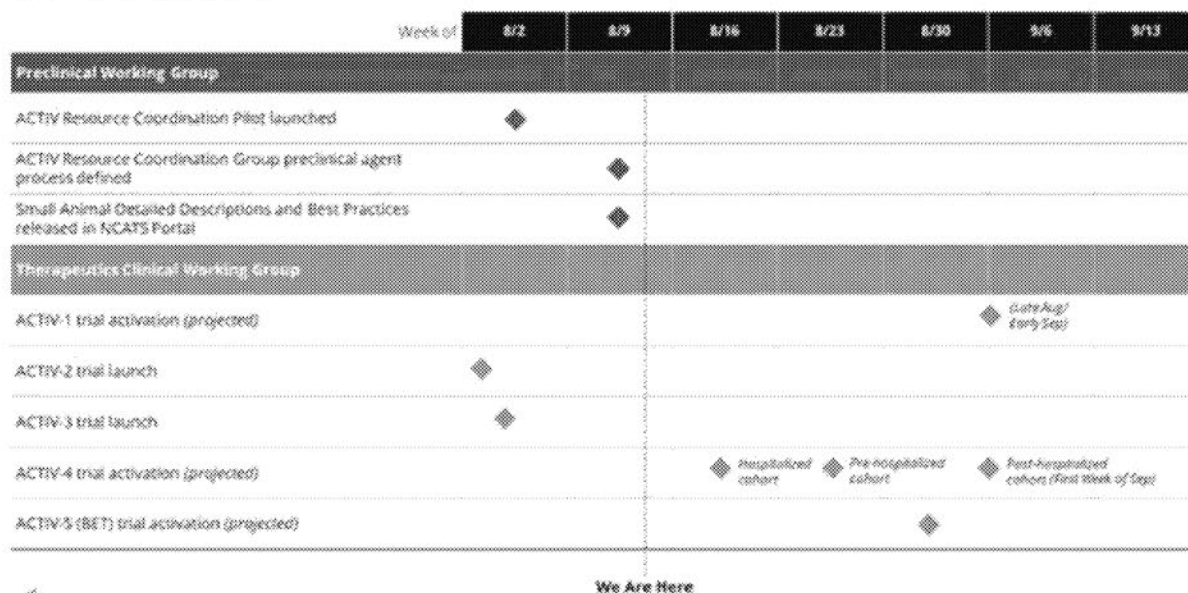
Let me reforward the note from Amy Patterson.

From: Elsaid, Olivia <oelsaid@deloitte.com>
Sent: Thursday, August 13, 2020 3:07 PM
To: Parker, Ashley (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6]
Subject: RE: ACTIV EC Pre-call

Hi Ashley,

The latest information we received from Andrei is that ACTIV-4 hospitalized is expected launch the week of August 17, pre-hospitalized the week of August 24 and post-hospitalized the first week of September. That's what I have reflected in the milestone slide below, but if you have heard more recent information that says August 27 then I'm happy to adjust this. I'm attaching the latest email chain on this topic that I have, but let me know if you think it should still be adjusted!

ACTIV Milestones



Olivia Elsaid

Deloitte Consulting LLP

Tel/Direct: [b6]

Mobile: [b6]

www.deloitte.com

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Thursday, August 13, 2020 2:53 PM

To: Elsaid, Olivia <oesaid@deloitte.com>; Wholley, David (FNIH) [T] [b6]

Subject: [EXT] RE: ACTIV EC Pre-call

Hi Olivia,

I am looking at the timeline for the ACTIV-4 hospitalized trial – we have this down to launch on 8/27. I'm not sure about the pre-hospitalized but I can ask Amy.

I think we need reflect the later launch date on the slide.

Thanks,
Ashley

From: Elsaid, Olivia <oesaid@deloitte.com>

Sent: Thursday, August 13, 2020 10:45 AM

To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]

Subject: RE: ACTIV EC Pre-call

That's a good point, David! I've updated those accordingly to move the timeline out to the week of September 13 to avoid any confusion and matched the dates to the statuses we show for each of the ACTIV trials on another slide. Please note that for the ACTIV-4 post-hospitalized cohort, the latest date I have for activation is the first of week of September from the exchange with Andrei, but please let me know if you've heard any new information and I can update that.

Additionally, I added ACTIV-5 (BET) to this slide since we decided to move forward with this naming in the rest of the Tx Clinical section. Please let me know if you have any questions of changes based on the attached.

Thank you!
Olivia

Olivia Elsaid

Deloitte Consulting LLP

Tel/Direct: [b6] Mobile: [b6]
www.deloitte.com

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, August 13, 2020 9:50 AM
To: Elsaid, Olivia <oesaid@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: [EXT] RE: ACTIV EC Pre-call

The third slide gives the impression that ACTIV-1 and the third arm of ACTIV-4 will both begin by the end of August, but both of these will occur sometime between September 1-15 from what I have heard. I would find a way to show that on the slides: either extend the timeline through Sept 15 or put an arrow pointing right next to each of the existing diamonds for those trials, with the relevant projected date below in italics. Thanks, David

From: Elsaid, Olivia <oesaid@deloitte.com>
Sent: Thursday, August 13, 2020 9:34 AM
To: Parker, Ashley (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6]
Subject: RE: ACTIV EC Pre-call

Hi Ashley,

Please find attached a slightly updated version of the three slides. David – let me know if you see any further changes to these.

Thank you!
Olivia

Olivia Elsaid

Deloitte Consulting LLP

Tel/Direct: [b6] Mobile: [b6]
www.deloitte.com

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 13, 2020 8:57 AM
To: Wholley, David (FNIH) [T] [b6] Elsaid, Olivia <oesaid@deloitte.com>
Subject: [EXT] RE: ACTIV EC Pre-call


Good morning David and Olivia,

We will share the attendee, agenda, and milestones slide for Dr. Collins' meeting with the Secretary – I just wanted to confirm that we have no additional changes on those slides.

Thank you,
Ashley

Attendees for ACTIV Executive Committee Meeting

ACTIV EXECUTIVE COMMITTEE		ACTIV WORKING GROUP CO-CHAIRS		NON-PROFIT	
	Francis Collins*		Christine Colvis Mike Kurilla		Maria Freire
	Paul Stoffels*		Sarah Read	PROGRAM MANAGEMENT	
	Anthony Fauci		[Doug Lowy]		
	Gary Gibbons		Eric Hughes		
	Gary Disbrow		John Young		
	Janet Woodcock		Betty Desrosiers	 David Wholley Joe Menetaki Stacey Adams Karen Tountas Michael Santos Stephanie James Margaret Anderson Nina Gonzalez Benjamin Stratton Olivia Elsaid Jonathan Wachel Rosa Alvarez Helen Chen Brett Tolman	
	Peter Marks		[Kathrin Jansen]		
	William Pan				
	Mikael Dolsten				
	Andrew Plump				

 **FNIH** Notes: † Denotes a leader not able to attend; * Denotes ACTIV Executive Committee Co-Chair

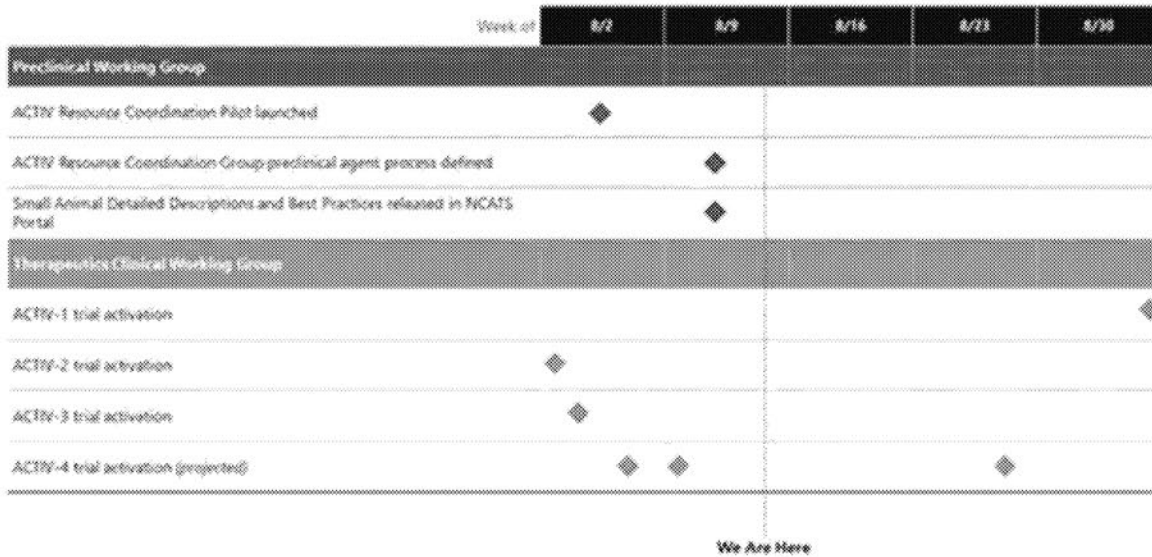
Confidential and Pre-decisional

Agenda

TIME	TOPIC	SPEAKER(S)
12:00 – 12:05 PM 5 mins	Introduction and General Updates on ACTIV	Francis Collins (NIH) Paul Stoffels (J&J)
12:05 – 12:10 PM 5 mins	Progress on Action Items from Previous Meetings	David Wholley (FNIH)
12:10 – 12:30 PM 20 mins	Working Group Updates and Q&A ACTIV Preclinical	Christine Colvis (NCATS), John Young (Roche)
12:30 – 12:50 PM 20 mins	ACTIV Therapeutics Clinical	Sarah Read (NIAID), Eric Hughes (Novartis)
12:50 – 1:00 PM 10 mins	Milestones and Discussion	Francis Collins (NIH) David Wholley (FNIH)

 **FNIH**

ACTIV Milestones



From: Wholley, David (FNIH) [T] [b6]

Sent: Wednesday, August 12, 2020 11:54 AM

To: Melencio, Cheryl (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Margaret <marganderson@deloitte.com>; Chen, Helen <qingchen@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; James, Stephanie (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Stratton, Benjamin <bstratton@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Hawk, Harrison <hhawk@deloitte.com>; Colvis, Christine (NIH/NCATS) [E] [b6]

Cc: Wood, Gretchen (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]

Subject: RE: ACTIV EC Pre-call

Importance: High

Please see attached the proposed slides and attendee list for our pre-call.

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6]

Sent: Tuesday, July 21, 2020 2:04 PM

To: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Benjamin; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Hawk, Harrison; Colvis, Christine (NIH/NCATS) [E]

Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]

Subject: ACTIV EC Pre-call

When: Wednesday, August 12, 2020 12:00 PM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: see webex below

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/5/2020 11:15:55 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Patterson, Amy (NIH/NHLBI) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=afad1ca74b3e449d8b4f3191d65bb70f-pattersa]; Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]; Lane, Cliff (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2d7e368a3137473bbce161547a82f2de-clane]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]
Subject: Re: Report on Today's C3PO and JHU/DOD Call

Hi Francis,

We need to change the Hopkins number of test to 20-25K test. The other numbers are correct.

Thanks,
Ashley

On Aug 5, 2020, at 6:23 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi again,

So adding up the needs, here's what I have:

C3PO – 120 machines, 15,000 test kits
Hopkins – 30 machines, 15,000 test kits
ACTIV-2 – 55 machines, 3275 test kits

Please confirm those numbers are correct.

Francis

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 4, 2020 8:28 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Patterson, Amy (NIH/NHLBI) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]
Lane, Cliff (NIH/NIAID) [E] [b6]
Subject: RE: Report on Today's C3PO and JHU/DOD Call

We are confirming with Nicole Kilgore. Rough estimate for now – they have 30 sites, one machine per site? 30 machines and 15K test.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, August 4, 2020 8:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Patterson, Amy (NIH/NHLBI) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]
[b6] > Lane, Cliff (NIH/NIAID) [E] [b6]
Subject: RE: Report on Today's C3PO and JHU/DOD Call

How many Abbott ID machines would JHU need?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, August 4, 2020 7:14 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Patterson, Amy (NIH/NHLBI) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E]
[b6]; Lane, Cliff (NIH/NIAID) [E] [b6]
Subject: Report on Today's C3PO and JHU/DOD Call

Hi Francis,

On behalf of the group, thank you for pulling the C3PO and JHU trial teams together to discuss options to work together to accelerate CP trials for outpatients. We've made progress and developed a few (DRAFT) options (the team is working on refining) that will be discussed individually with PIs tomorrow and we plan to re-assemble the full group tomorrow afternoon or no later than Thursday.

b5

b5

Cc'ing Amy, Mike, and Cliff for any additional input.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/12/2020 12:58:25 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ACTIV Daily Update 20200812.pptx

Yes – we can do this, after it's in better shape of course – thank you, Maria!

Ashley

From: Freire, Maria (FNIH) [T] <b6>
Sent: Wednesday, August 12, 2020 8:55 AM
To: Parker, Ashley (NIH/OD) [E] <b6>
Cc: Wholley, David (FNIH) [T] <b6>
Subject: Re: ACTIV Daily Update 20200812.pptx

Ashley, I love this chart, as you know. Do you think it would be possible to get some of the NIH graphics folks make it spectacular so we can put it on the ACTIV webpage? M.

On Aug 12, 2020, at 8:29 AM, Parker, Ashley (NIH/OD) [E] <b6> wrote:

Please see the attached working draft of the ACTIV grid.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <b6>
Sent: Wednesday, August 12, 2020 7:17 AM
To: Collins, Francis (NIH/OD) [E] <b6> Tabak, Lawrence (NIH/OD) [E] <b6>; Lane, Cliff (NIH/NIAID) [E] <b6>; Freire, Maria (FNIH) [T] <b6>; Austin, Christopher (NIH/NCATS) [E] <b6>; Parker, Ashley (NIH/OD) [E] <b6> Anderson, James (NIH/OD) [E] <b6>
Subject: ACTIV Daily Update 20200812.pptx

For this morning's war room, Wednesday August 12. N.B. Maria may not be able to join.
<DRAFT ACTIV Checkerboard-WorkingFile 081220.pptx>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/13/2020 1:46:46 PM
To: Elsaid, Olivia [oelsaid@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: ACTIV EC Pre-call

Thanks!

From: Elsaid, Olivia <oelsaid@deloitte.com>

Sent: Thursday, August 13, 2020 9:34 AM

To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]

Subject: RE: ACTIV EC Pre-call

Hi Ashley,

Please find attached a slightly updated version of the three slides. David – let me know if you see any further changes to these.

Thank you!

Olivia

Olivia Elsaid

Deloitte Consulting LLP

Tel/Direct: [b6] | Mobile: [b6]
www.deloitte.com

From: Parker, Ashley (NIH/OD) [E] [b6]

Sent: Thursday, August 13, 2020 8:57 AM

To: Wholley, David (FNIH) [T] [b6]; Elsaid, Olivia <oelsaid@deloitte.com>

Subject: [EXT] RE: ACTIV EC Pre-call

Good morning David and Olivia,

We will share the attendee, agenda, and milestones slide for Dr. Collins' meeting with the Secretary – I just wanted to confirm that we have no additional changes on those slides.

Thank you,

Ashley

Attendees for ACTIV Executive Committee Meeting

ACTIV EXECUTIVE COMMITTEE		ACTIV WORKING GROUP CO CHAIRS		NON-PROFIT	
 National Institutes of Health	Francis Collins*	 National Center for Advancing Translational Sciences	Christine Colvis Mike Kurilla	 FNIH	Maria Freire
 J&J	Paul Stoffels*	 National Institutes of Health	Sarah Read	PROGRAM MANAGEMENT	
 National Institutes of Health	Anthony Fauci	 National Institutes of Health	[Doug Lowy]		
 National Institutes of Health	Gary Gibbons	 National Institutes of Health	Eric Hughes		
 National Institutes of Health	Gary Disbrow	 NOVARTIS	John Young		
 FNIH	Janet Woodcock	 Roche	Betsy Desrosiers	 FNIH	
 FDA	Peter Marks	 MERCK	[Kathrin Jansen]		
 Roche	William Pao	 Pfizer			
 Pfizer	Mikael Dolsten				
 Roche	Andrew Plump				

 FNIH Notes: [D] Denotes a leader not able to attend; * Denotes ACTIV Executive Committee Co-Chair

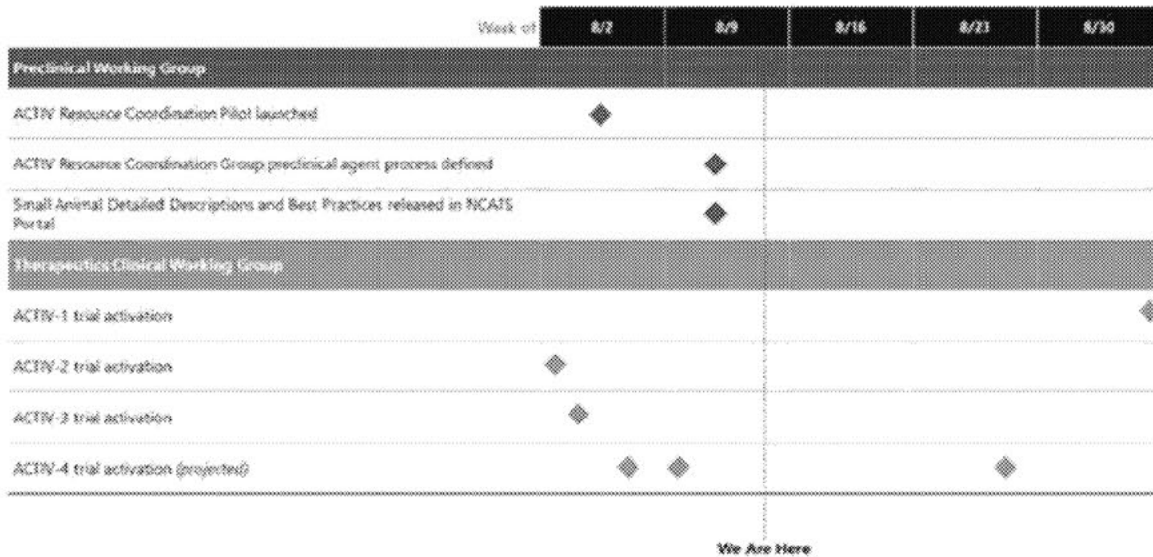
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 FNIH

ACTIV Milestones



From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, August 12, 2020 11:54 AM
To: Melencio, Cheryl (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Margaret <marganderson@deloitte.com>; Chen, Helen <qingchen@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; James, Stephanie (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] <jmenetski@fnihi.org>; Santos, Michael (FNIH) [T] [b6]; Stratton, Benjamin <bstratton@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Tountas, Karen (FNIH) [T] [b6]; Wachtel, Jonathan <jwachtel@deloitte.com>; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Gadbois, Ellen (NIH/OD) [E] [b6]; Culp, Michelle (NIH/OD) [E] [b6]; Hawk, Harrison <hhawk@deloitte.com>; Colvis, Christine (NIH/NCATS) [E] [b6]
Cc: Wood, Gretchen (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]; Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]
Subject: RE: ACTIV EC Pre-call
Importance: High

Please see attached the proposed slides and attendee list for our pre-call.

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Tuesday, July 21, 2020 2:04 PM
To: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Benjamin; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Hawk, Harrison; Colvis, Christine (NIH/NCATS) [E]
Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]
Subject: ACTIV EC Pre-call
When: Wednesday, August 12, 2020 12:00 PM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/13/2020 8:38:02 PM
To: Elsaid, Olivia [oelsaid@deloitte.com]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: ACTIV EC Pre-call

Thanks, Olivia!
Ashley

From: Elsaid, Olivia <oelsaid@deloitte.com>

Sent: Thursday, August 13, 2020 4:10 PM

To: Wholley, David (FNIH) [T] <dwholley@fnihi.org>; Parker, Ashley (NIH/OD) [E]

b6

Cc: Adam, Stacey (FNIH) [T]

b6

Subject: RE: ACTIV EC Pre-call

Hi David,

Ashley and I just connected over the phone and decided to move the ACTIV-4 hospitalized cohort to show projected launch during the week of August 24th rather than the week before that Andrei had noted. Given that the press briefing is scheduled for August 27th and that Andrei said the week of the 24th today on our WG call, we think that is a safer bet.

Just wanted to close the loop on this given the back and forth, but please let us know if you have any concerns. The dates in the attached milestone slide for ACTIV-4 should be the latest.

Ashley – please find the updated slides for the Secretary attached here.

Many thanks!
Olivia

Olivia Elsaid

Deloitte Consulting LLP

Tel/Direct: +1 617 437 3197 | Mobile:

b6

www.deloitte.com

From: Parker, Ashley (NIH/OD) [E]

b6

Sent: Thursday, August 13, 2020 3:28 PM

To: Wholley, David (FNIH) [T]; Elsaid, Olivia <oelsaid@deloitte.com>

b6

Subject: [EXT] RE: ACTIV EC Pre-call

OK. Sorry Olivia and David – the launch of these trials are a moving target and constantly changing.

David – I know the press briefings for ACTIV-4 is scheduled for 8/27 based on the note from Renate and we had this as the launch date for hospitalized patients, however since NHLBI has confirmed those dates, I guess it's safe to leave them. I did write a note to Amy to ask for confirmation given this is going to the Secretary.

Thanks so much,
Ashley

APAR0000011014

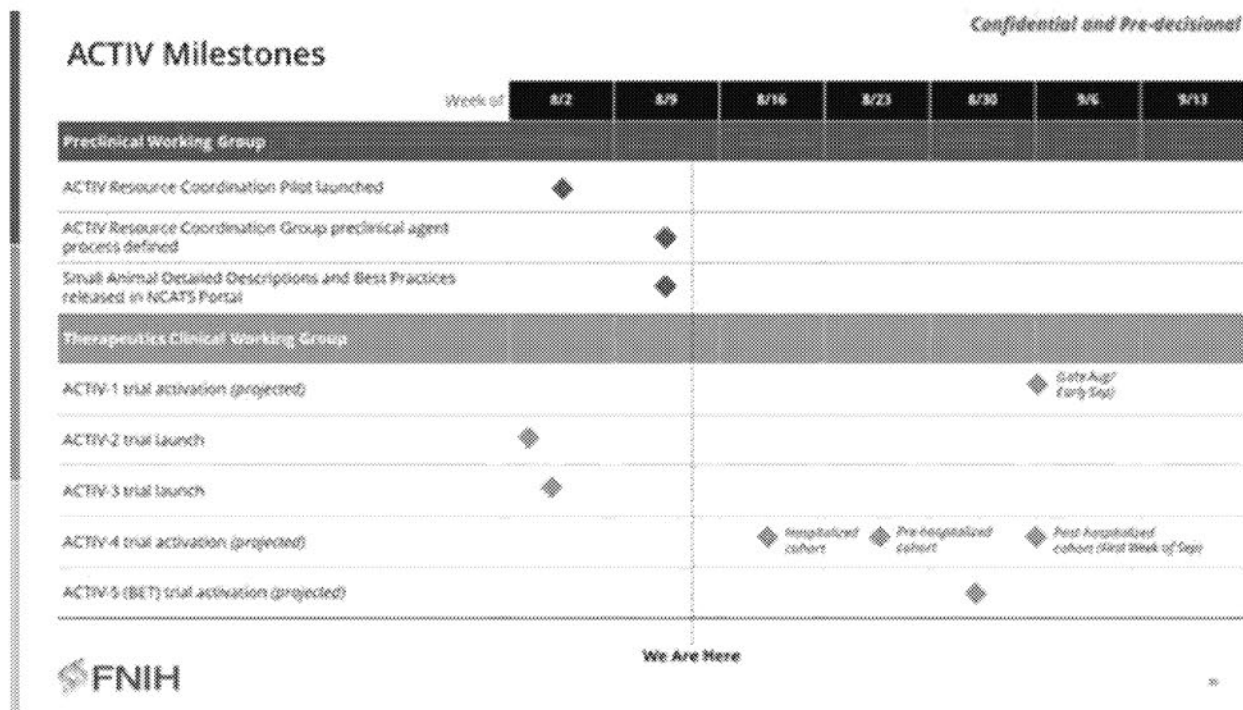
From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, August 13, 2020 3:19 PM
To: Elsaid, Olivia <oesaid@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: ACTIV EC Pre-call

Let me reforward the note from Amy Patterson.

From: Elsaid, Olivia <oesaid@deloitte.com>
Sent: Thursday, August 13, 2020 3:07 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: ACTIV EC Pre-call

Hi Ashley,

The latest information we received from Andrei is that ACTIV-4 hospitalized is expected launch the week of August 17, pre-hospitalized the week of August 24 and post-hospitalized the first week of September. That's what I have reflected in the milestone slide below, but if you have heard more recent information that says August 27 then I'm happy to adjust this. I'm attaching the latest email chain on this topic that I have, but let me know if you think it should still be adjusted!



Olivia Elsaid
Deloitte Consulting LLP
Tel/Direct: +1 617 437 3197 | Mobile: [b6]
www.deloitte.com

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, August 13, 2020 2:53 PM
To: Elsaid, Olivia <oesaid@deloitte.com>; Wholley, David (FNIH) [T] [b6]
Subject: [EXT] RE: ACTIV EC Pre-call

Hi Olivia,

I am looking at the timeline for the ACTIV-4 hospitalized trial – we have this down to launch on 8/27. I'm not sure about the pre-hospitalized but I can ask Amy.

I think we need reflect the later launch date on the slide.

Thanks,
Ashley

From: Elsaid, Olivia <oelsaid@deloitte.com>

Sent: Thursday, August 13, 2020 10:45 AM

To: Wholley, David (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]

Subject: RE: ACTIV EC Pre-call

That's a good point, David! I've updated those accordingly to move the timeline out to the week of September 13 to avoid any confusion and matched the dates to the statuses we show for each of the ACTIV trials on another slide. Please note that for the ACTIV-4 post-hospitalized cohort, the latest date I have for activation is the first of week of September from the exchange with Andrei, but please let me know if you've heard any new information and I can update that.

Additionally, I added ACTIV-5 (BET) to this slide since we decided to move forward with this naming in the rest of the Tx Clinical section. Please let me know if you have any questions of changes based on the attached.

Thank you!
Olivia

Olivia Elsaid

Deloitte Consulting LLP

Tel/Direct: +1 617 437 3197 | Mobile: [b6]

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From: Wholley, David (FNIH) [T] [b6]

Sent: Thursday, August 13, 2020 9:50 AM

To: Elsaid, Olivia <oelsaid@deloitte.com>; Parker, Ashley (NIH/OD) [E] [b6]

Subject: [EXT] RE: ACTIV EC Pre-call

The third slide gives the impression that ACTIV-1 and the third arm of ACTIV-4 will both begin by the end of August, but both of these will occur sometime between September 1-15 from what I have heard. I would find a way to show that on the slides: either extend the timeline through Sept 15 or put an arrow pointing right next to each of the existing diamonds for those trials, with the relevant projected date below in italics. Thanks, David

From: Elsaid, Olivia <oelsaid@deloitte.com>

Sent: Thursday, August 13, 2020 9:34 AM

To: Parker, Ashley (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]

Subject: RE: ACTIV EC Pre-call

Hi Ashley,

Please find attached a slightly updated version of the three slides. David – let me know if you see any further changes to these.

Thank you!
Olivia

Olivia Elsaid

Deloitte Consulting LLP

From: Parker, Ashley (NIH/OD) [E] b6
Sent: Thursday, August 13, 2020 8:57 AM
To: Wholley, David (FNIH) [T] b6; Elsaïd, Olivia <oelsaid@deloitte.com>
Subject: [EXT] RE: ACTIV EC Pre-call

Good morning David and Olivia,

We will share the attendee, agenda, and milestones slide for Dr. Collins' meeting with the Secretary – I just wanted to confirm that we have no additional changes on those slides.

Thank you,
Ashley

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Attendees for ACTIV Executive Committee Meeting

ACTIV EXECUTIVE COMMITTEE		ACTIV WORKING GROUP CO-CHAIRS		NON-PROFIT	
	Francis Collins*		Christine Colvin Mike Kurilla		Maria Freire
	Paul Stoffels*		Sarah Read		
	Anthony Fauci		[Doug Lowy]		
	Gary Gibbons		Eric Hughes		
	Gary Disbrow		John Young		
	Janet Woodcock		Betty Desrosiers		
	Peter Marks		[Kathrin Jansen]		
	William Pao				
	Mikael Dolsten				
	Andrew Pump				

PROGRAM MANAGEMENT

David Wholley
Joe Menertaki
Stacey Adams
Karen Fountas
Michael Santon
Stephanie James
Margaret Anderson
Nina Gonzalez
Benjamin Stratton
Olivia Elsaïd
Jonathan Wachel
Rosa Alvarez
Helen Chen
Brett Tolman

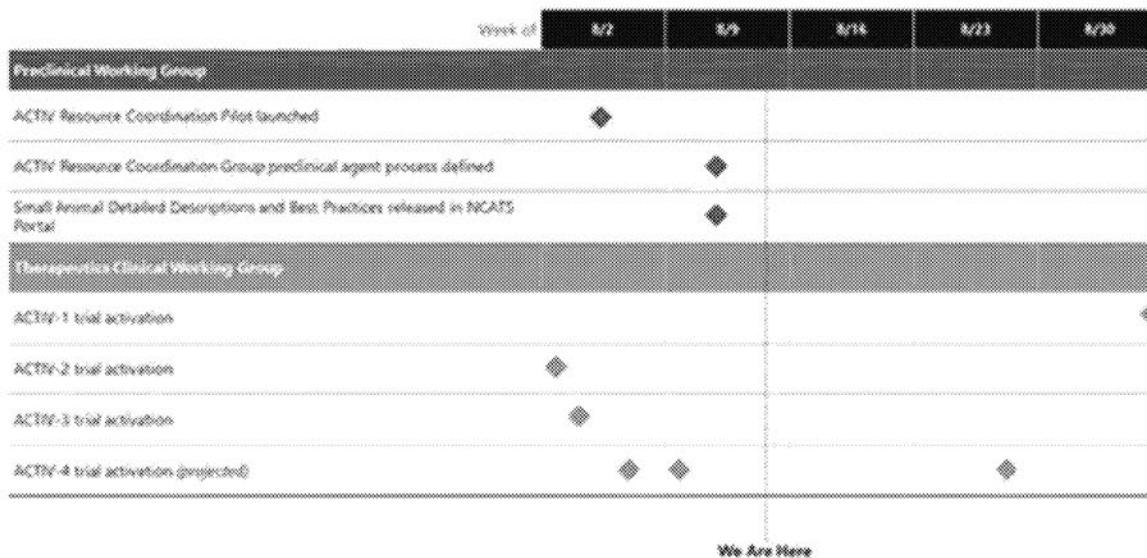
Agenda

TIME	TOPIC	SPEAKER(S)
12:00 – 12:05 PM 5 mins	Introduction and General Updates on ACTIV	Francis Collins (NIH) Paul Stoffels (J&J)
12:05 – 12:10 PM 5 mins	Progress on Action Items from Previous Meetings	David Wholley (FNIH)
12:10 – 12:30 PM 20 mins	Working Group Updates and Q&A ACTIV Preclinical	Christine Colvis (NCATS), John Young (Roche)
12:30 – 12:50 PM 20 mins	ACTIV Therapeutics Clinical	Sarah Read (NIAID), Eric Hughes (Novartis)
12:50 – 1:00 PM 10 mins	Milestones and Discussion	Francis Collins (NIH) David Wholley (FNIH)



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ACTIV Milestones



From: Wholley, David (FNIH) [T] b6

Sent: Wednesday, August 12, 2020 11:54 AM

To: Melencio, Cheryl (FNIH) [T] b6; Adam, Stacey (FNIH) [T] b6; Alvarez, Rosa <rosalvarez@deloitte.com>; Anderson, Margaret <marganderson@deloitte.com>; Chen, Helen <qingchen@deloitte.com>; Elsaid, Olivia <oelsaid@deloitte.com>; Gonzalez, Nina <ningonzalez@deloitte.com>; James, Stephanie (FNIH) [T] b6; Menetski, Joseph (FNIH) [T] b6; Santos, Michael (FNIH) [T] b6; Stratton, Benjamin <bstratton@deloitte.com>; Tolman, Brett <btolman@deloitte.com>; Tountas, Karen (FNIH) [T] b6; Wachtel, Jonathan <jwachtel@deloitte.com>; Collins, Francis (NIH/OD) [E] b6; Tabak, Lawrence (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6; Gadbois, Ellen (NIH/OD) [E] b6; Culp, Michelle (NIH/OD) [E] b6; Hawk, Harrison <hhawk@deloitte.com>; Colvis, Christine (NIH/NCATS) [E]

b6

Cc: Wood, Gretchen (NIH/OD) [E] [b6]; McManus, Ayanna (NIH/OD) [E] [b6]
Burrus-Shaw, Cyndi (NIH/OD) [E] [b6]; Simon, Dina (NIH/OD) [C] [b6]
Subject: RE: ACTIV EC Pre-call
Importance: High

Please see attached the proposed slides and attendee list for our pre-call.

-----Original Appointment-----

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Tuesday, July 21, 2020 2:04 PM
To: Melencio, Cheryl (FNIH) [T]; Adam, Stacey (FNIH) [T]; Alvarez, Rosa; Anderson, Margaret; Chen, Helen; Elsaid, Olivia; Gonzalez, Nina; James, Stephanie (FNIH) [T]; Menetski, Joseph (FNIH) [T]; Santos, Michael (FNIH) [T]; Stratton, Benjamin; Tolman, Brett; Tountas, Karen (FNIH) [T]; Wachtel, Jonathan; Wholley, David (FNIH) [T]; Collins, Francis (NIH/OD) [E]; Tabak, Lawrence (NIH/OD) [E]; Parker, Ashley (NIH/OD) [E]; Gadbois, Ellen (NIH/OD) [E]; Culp, Michelle (NIH/OD) [E]; Hawk, Harrison; Colvis, Christine (NIH/NCATS) [E]
Cc: Wood, Gretchen (NIH/OD) [E]; McManus, Ayanna (NIH/OD) [E]; Burrus-Shaw, Cyndi (NIH/OD) [E]; Simon, Dina (NIH/OD) [C]
Subject: ACTIV EC Pre-call
When: Wednesday, August 12, 2020 12:00 PM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).
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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/26/2021 10:06:32 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Appell, Evan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=user7ee69e83]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: ACTIV & NIH Data Sharing and Collaboration

Thanks, David!

Ashley

From: Wholley, David (FNIH) [T] [b6]
Sent: Friday, February 26, 2021 3:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Appell, Evan <eappell@deloitte.com>; Adam, Stacey (FNIH) [T] [b6]
Subject: FW: ACTIV & NIH Data Sharing and Collaboration

Hi Ashley:

As have heard on war room earlier this week, we had a request from Yves Rosenberg to access information on the agents prioritized by the ACTIV Therapeutics Working Group in order to inform prioritization discussions at NHLBI. In response the ACTIV FNIH/Deloitte team has created a shared site on a platform called Basecamp which can be used to share information between our groups on which agents have been reviewed as potential treatments / therapeutics for COVID-19. The site includes summaries of the results of the deliberations of the ACTIV Agent Prioritization Workgroup on those agents that went beyond the initial triage stage, anonymized to remove the reviewer names. Given your role and the kinds of queries about the prioritization process you get, I thought you could use access to this.

Below please find an overview of how to access the Basecamp site, along with details on the materials that have already been uploaded.

As you know, we are also granting access to specified individuals within the major ICs involved in ACTIV: NIAID, NHLBI, NINDS, and NCATS.

Please let me and Evan Appell of Deloitte Consulting know if you have any questions or difficulty accessing the site, and our team can help to troubleshoot as needed. Thanks,

David

Accessing Basecamp:

1. In order to access Basecamp, the individual must **create an account** on Basecamp (*only if you do not have a Basecamp account already)
 - o This can easily be done by following this link:
https://3.basecamp.com/signup/account/new?plan=one_v1
2. Once the individual has created their account, they should inform the ACTIV team so that we can **grant them permission** to access the “ACTIV / NIH Data Sharing & Collaboration” Basecamp site
 - o The individual will then receive an email **directly from Basecamp** (not from FNIH) alerting them that they have been given access to the “ACTIV / NIH Data Sharing & Collaboration” Basecamp site

3. Once the individual has been granted permission to the site, they can **access it through the email that was sent to them or by following this link:** <https://3.basecamp.com/3948057/projects/21021910>

Materials Available on the Basecamp site:

4. Once an individual enters the "ACTIV / NIH Data Sharing & Collaboration" Basecamp site, they will see a "**Docs & Files**" folder which contains a **PowerPoint file** titled "*ACTIV_TX-Preclinical and Clinical_Agent Prioritization Summary_vSHARE*"
 - They can then download this file from Basecamp, and view it on their desktop app
5. The file includes a **summary of all agents that have been reviewed** by the ACTIV Therapeutics-Clinical Agent Prioritization Sub Teams.

A few brief notes on what is included in this file:

 - There are ~200 reviews of Antiviral, Immune Modulator, and Symptomatic / Supportive agents that have been evaluated by ACTIV
 - We have included a summary of the scoring criteria that were used to assess each agent at the very front of the deck
 - There is a table of contents in the beginning of the deck listing all of the agents that have been reviewed (which also includes hyperlinks that can be used to navigate directly to the detailed review of any particular agent)

David Wholley
Senior Vice-President, Research Partnerships
Foundation for the National Institutes of Health
b6 | fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852



From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/4/2020 1:32:14 PM
To: Kilgore, Nicole R CIV USARMY (USA) [b6]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]
Subject: Re: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)

Great! Thank you, Nicole for your flexibility and we look forward to the discussion.

Thanks,
Ashley

> On Aug 4, 2020, at 9:27 AM, Kilgore, Nicole R CIV USARMY (USA) [b6] wrote:

>
> CLASSIFICATION: UNCLASSIFIED

> Hi,

> We will make the proposed time work.

> Regards,

> Nicole

> Nicole Kilgore, MS, PMP

> Deputy Joint Project Manager

> JPM CBRN Medical

> 1564 Freedman Dr, Fort Detrick, MD 21702

> Ph- [b6]

> Cell [b6]

> Fax- 301-619-7230

> email - [b6]

> -----Original Message-----

> From: Parker, Ashley (NIH/OD) [E] [b6]

> Sent: Tuesday, August 4, 2020 8:44 AM

> To: Kilgore, Nicole R CIV USARMY (USA) [b6]

> Cc: McManus, Ayanna (NIH/OD) [E] [b6]

> Subject: RE: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)

> Hi Nicole,

> Unfortunately, 1:30pm was the only time available for Dr. Collins' schedule today. Will you be able to make this work?

> I am cc'ing Ayanna McManus who handles Dr. Collins' schedule.

> Thank you and apologies for the short notice, Ashley

> Ashley Parker, Ph.D.

> Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) Office of the Director | National Institutes of Health

> Tel: [b6]

> -----Original Message-----

> From: Kilgore, Nicole R CIV USARMY (USA) [b6]

> Sent: Tuesday, August 4, 2020 8:36 AM

> To: Kurilla, Michael (NIH/NCATS) [E] [b6]

> Cc: Parker, Ashley (NIH/OD) [E] [b6]; Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA) [b6]; Collins, Francis (NIH/OD) [E] [b6]; Schmitt, Clare (NIH/NCATS) [E] [b6]; Atkinson, Jane (NIH/NCATS) [E] [b6]

> Subject: RE: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)

>
> CLASSIFICATION: UNCLASSIFIED
>
> Good morning Ashley,
>
> Our availability today is as follows.
>
> 12-1 and 3:30-5:00.
>
> Thanks,
> Nicole
>
> Nicole Kilgore, MS, PMP
> Deputy Joint Project Manager
> JPM CBRN Medical
> 1564 Freedman Dr, Fort Detrick, MD 21702
> Ph- [b6]
> Cell [b6]
> Fax- 301-619-7230
> email - [b6]
>
>
> -----Original Message-----
> From: Kurilla, Michael (NIH/NCATS) [E] [b6]
> Sent: Monday, August 3, 2020 6:50 PM
> To: Kilgore, Nicole R CIV USARMY (USA) [b6]
> Cc: Parker, Ashley (NIH/OD) [E] [b6]; Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA) [b6]
> [b6]; Collins, Francis (NIH/OD) [E] [b6]; Schmitt, Clare (NIH/NCATS) [E] [b6]; Atkinson, Jane (NIH/NCATS) [E] [b6]
> Subject: RE: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)
>
> Nicole,
>
> Good to reconnect (although I would have preferred under different circumstances). We have had quite a bit of discussion regarding a number of convalescent plasma trials and would like to explore the possibility of harmonizing the Sullivan trial (NCT04373460) with the C3PO trial sponsored by NHLBI/NIH that is quite similar. Both trials could benefit from access to rapid POC diagnostics and several other enhancements.
>
> Would it be possible to schedule a time tomorrow with your and/or other relevant DOD staff to discuss options?
>
> Ashley Parker will handle scheduling.
>
> Michael G Kurilla, MD-PhD
> Director, Division of Clinical Innovation National Center for Advancing Translational Sciences (NCATS)
> National Institutes of Health
> 6701 Democracy Blvd, Room 934
> Bethesda, MD 20892
>
> [b6]
>
> I'm not blessed or merciful. I'm just me. I've got a job to do and I do it.
> ...I'm there for the old and young, innocent and guilty, those who die together and those who die alone.
> ...in the end, I'm there for all of them.
> -Death, from Neil Gaiman's Sandman #20 Façade
>
> -----Original Message-----
> From: Kilgore, Nicole R CIV USARMY (USA) [b6]
> Sent: Sunday, August 2, 2020 10:00 PM
> To: Collins, Francis (NIH/OD) [E] [b6]
> Cc: Parker, Ashley (NIH/OD) [E] [b6]; Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA) [b6]
> [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]
> Subject: RE: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)
>
> CLASSIFICATION: UNCLASSIFIED
>
> Dear Drs Collins and Kurilla,
>
> The ongoing study is being funded under a contract with the DOD-JPEO. I believe there are opportunities for collaboration for accelerating the study. If this is something you would like to pursue, I suggest we discuss further on the best approach to move forward.
>
> Look forward to talking soon.
>
> Regards,
> Nicole
>

[T] [b6]; Wholley, David (FNIH) [T] [b6]; Marks, Peter (FDA/CBER)
[b6]; Hoots, W. Keith (NIH/NHLBI) [E] [b6]; Glynn, Simone
(NIH/NHLBI) [E] [b6]; Groesch, Mary (NIH/NHLBI) [E] [b6]; Shipp,
Allan (NIH/NHLBI) [E] [b6]; Punturieri, Antonello (NIH/NHLBI) [E]
[b6]; David Sullivan [b6];
Shmuel Shoham [b6]; Dan Hanley [b6]; Ralph Sacco
[b6]; Jayaweera, Dushyantha (NIH) [b6];
[b6]; Santos, Michael
(FNIH) [T] [b6]; Roberts David
[b6]; Homer, Mary (OS/ASPR/BARDA) [b6];
[b6]; Arturo Casadevall
> Cc: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E]

> Subject: CP RCT Meeting Summary -- and urgent timeline

> Dear Colleagues,

> I greatly appreciate everyone who was available to join the convalescent plasma RCT discussion
yesterday on such short notice. As promised, attached is the meeting summary. I am asking the principal
investigators from each of the RCTs to send responses to the questions outlined below to Dr. Ashley
Parker, ashley.parker@nih.gov < Caution-mailto:ashley.parker@nih.gov > cc'ing me by noon tomorrow, July
30.

> Here is what I'm looking for:

- > * If resources were unlimited, what could be done to accelerate enrollment?
- > * What barriers would need to be overcome?
- > * How many participants could be enrolled by August 31? By September 30?
- > * When would a read-out of the study be possible?
- > * What would that cost?

> Many of you have already provided clinical trial information in the attached excel spreadsheet, many
thanks.

> Thank you,

> Francis

> Francis S. Collins, M.D., Ph.D.

> Director, National Institutes of Health

> CLASSIFICATION: UNCLASSIFIED

> CLASSIFICATION: UNCLASSIFIED

> CLASSIFICATION: UNCLASSIFIED

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 8/3/2020 3:39:11 PM
To: Kurilla, Michael (NIH/NCATS) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc4e85061e3943b9b8ad3f426727861f-mkurilla]
Subject: RE: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)

Hi Mike,

Francis has shared the detailed budget JHU submitted and the note from DOD with the ACTIV war room, Chris Austin, Cliff Lane, et al. We had our regular 8am call this morning however Chris was not on the call and we haven't received feedback via email.

I sent you a note this morning asking what is NCATS thoughts on this? -- Is this approach to convalescent plasma in outpatients likely to be successful? It would be useful if Chris sends FC a reply with recommendations.

I am happy to flag as a follow up for FC but I think he wants to know the teams recommendation before responding/scheduling a call with Nicole.

Thanks,
Ashley

-----Original Message-----

From: Kurilla, Michael (NIH/NCATS) [E] [b6]
Sent: Monday, August 3, 2020 11:26 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)

Ashley,

Does Francis have any intention of responding?

I should add that I know Nicole and have worked with her in the past on a range of biodefense issues and so I anticipate that she would expect some type of response.

One other aspect to highlight is that I have learned that the JHU trials are activating 5 sites in tribal locations and so there might be an optics issue.

Michael G Kurilla, MD-PhD
Director, Division of Clinical Innovation National Center for Advancing Translational Sciences (NCATS)
National Institutes of Health
6701 Democracy Blvd, Room 934
Bethesda, MD 20892

[b6]

I'm not blessed or merciful. I'm just me. I've got a job to do and I do it.
...I'm there for the old and young, innocent and guilty, those who die together and those who die alone.
...in the end, I'm there for all of them.
-Death, from Neil Gaiman's Sandman #20 Façade

-----Original Message-----

From: Kilgore, Nicole R CIV USARMY (USA) [b6]
Sent: Sunday, August 2, 2020 10:00 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA) [b6]
Subject: RE: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline (UNCLASSIFIED)

CLASSIFICATION: UNCLASSIFIED

Dear Drs Collins and Kurilla,

The ongoing study is being funded under a contract with the DOD-JPEO. I believe there are opportunities for collaboration for accelerating the study. If this is something you would like to pursue, I suggest we discuss further on the best approach to move forward.

Look forward to talking soon.

Regards,
Nicole

APAR0000011056

Nicole Kilgore, MS, PMP
Deputy Joint Project Manager
JPM CBRN Medical
1564 Freedman Dr, Fort Detrick, MD 21702
Ph- [b6]
Cell [b6]
Fax- 301-619-7230
email - [b6]

-----Original Message-----

From: Dan Hanley [b6]
Sent: Sunday, August 2, 2020 7:59 PM
To: [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA) [b6]; Kilgore, Nicole R CIV USARMY (USA) [b6]; David Sullivan [b6]; Shmuel Shoham [b6]; Karen Lane [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Daniel Ford [b6]
Subject: [Non-DoD Source] Re: CP RCT Meeting Summary -- and urgent timeline

All active links contained in this email were disabled. Please verify the identity of the sender, and confirm the authenticity of all links contained within the message prior to copying and pasting the address to a Web browser.

Dear Dr Collins ,

Attached please find the details behind the request you directed us to provide for the specific needs to accelerate our outpatient trials. We have copied Ashely Parker and Mike Kurilla as requested.

As promised on our thursday submission we have added budgetary detail and rational. After discussion with our institutional officer and CTSA PI, Daniel Ford we can put this plan into action with verbal notification of intent to support. Thus we can begin this enhancement of effort immediately with the intent and likelihood of completing the trial on September 30 of this year as requested

Thank you for your interest in our 2 trials.

Dan Hanley
David Sullivan
Shmuel Shoham

From: Peleton [b6]
Date: Wednesday, July 29, 2020 at 2:10 PM
To: "Schmid, Kara E LTC USARMY DOD JPEO CBRND (USA)" [b6]
Subject: FW: CP RCT Meeting Summary -- and urgent timeline

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, July 29, 2020 1:54 PM
To: Tabak, Lawrence (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Lauer, Michael (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E] [b6]; Rutter, Joni (NIH/NCATS) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E] [b6]; Woodcock, Janet (FDA/CDER)

[b6]; Disbrow, Gary (OS/ASPR/BARDA) [b6]; Freire, Maria (FNIH)
 [T] [b6]; Wholley, David (FNIH) [T] [b6]; Marks, Peter (FDA/CBER)
 [b6]; Hoots, W. Keith (NIH/NHLBI) [E] [b6]; Glynn, Simone
 (NIH/NHLBI) [E] [b6]; Groesch, Mary (NIH/NHLBI) [E] [b6]; Shipp,
 Allan (NIH/NHLBI) [E] [b6]; Punturieri, Antonello (NIH/NHLBI) [E]
 [b6];
 [b6] David Sullivan [b6]
 Shmuel Shoham [b6]; Dan Hanley [b6]; Ralph Sacco
 [b6]; Jayaweera, Dushyantha (NIH) [b6]
 [b6]; Santos, Michael
 (FNIH) [T] [b6]; Roberts David
 [b6]; Homer, Mary (OS/ASPR/BARDA) [b6]
 [b6]; Arturo Casadevall
 [b6]
 Cc: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E]
 [b6]
 Subject: CP RCT Meeting Summary -- and urgent timeline

Dear Colleagues,

I greatly appreciate everyone who was available to join the convalescent plasma RCT discussion yesterday on such short notice. As promised, attached is the meeting summary. I am asking the principal investigators from each of the RCTs to send responses to the questions outlined below to Dr. Ashley Parker, ashley.parker@nih.gov < Caution-mailto:ashley.parker@nih.gov > cc'ing me by noon tomorrow, July 30.

Here is what I'm looking for:

- * If resources were unlimited, what could be done to accelerate enrollment?
- * What barriers would need to be overcome?
- * How many participants could be enrolled by August 31? By September 30?
- * When would a read-out of the study be possible?
- * What would that cost?

Many of you have already provided clinical trial information in the attached excel spreadsheet, many thanks.

Thank you,

Francis

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health

CLASSIFICATION: UNCLASSIFIED

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 7/28/2020 12:00:43 AM
To: Callaway, Clifton [b6]; Durkalski-Mauldin, Valerie L. [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Clif,

I will be sure to include this version. We greatly appreciate it.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



National Institutes of Health

From: Callaway, Clifton [b6]
Sent: Monday, July 27, 2020 6:18 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Durkalski-Mauldin, Valerie L. [b6]
Subject: Re: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Ashley

Val D noted that the DCC was incorrectly listed as USC and it is MUSC - I corrected this in the spreadsheet

The slide primary outcome is within 15 days (added that as well since I was emailing again).

Clif

From: Callaway, Clifton [b6]
Sent: Monday, July 27, 2020 17:19
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Ashley,

Here is one slide addressing those questions.
The spreadsheet is filled as well.

Please let me know what else you need.

Clif C

Clifton W. Callaway, MD, PhD

APAR0000011116

Professor and Executive Vice-Chair Emergency Medicine

Ronald D. Stewart Chair of Emergency Medicine Research

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 27, 2020 11:44
To: Callaway, Clifton [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Clif,

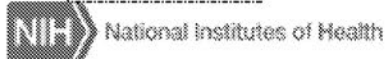
Thank you for sending your availability to attend the CP RCT meeting tomorrow.

Yes, please prepare a summary slide (5 mins) with the information requested below and complete the highlighted sections in the attached spreadsheet. We will collate the information received into a single document to be shared for the discussion tomorrow.

Would you be able to complete the highlighted information in the attached spreadsheet and send the single slide for C3PO by COB today? Apologies in advance for the quick turnaround.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



From: Callaway, Clifton [b6]
Sent: Monday, July 27, 2020 7:18 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Fw: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Ashley,

I will be sure to attend this call. We will decide who to present on behalf of the C3PO trial.

Shall we prepare a summary slide with the information outlined below?

Clif C

APAR0000011116

Clifton W. Callaway, MD, PhD

SIREN / C3PO trial

Professor and Executive Vice-Chair Emergency Medicine

Ronald D. Stewart Chair of Emergency Medicine Research

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Monday, July 27, 2020 06:54

To: Callaway, Clifton [b6]

b6

Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E]
[b6]; Lane, Cliff (NIH/NIAID) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E]
[b6]; Gibbons, Gary (NIH/NHLBI) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E]
[b6]; Rutter, Joni (NIH/NCATS) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E]
Woodcock, Janet (FDA/CDER) [b6]; Disbrow, Gary
(OS/ASPR/BARDA) [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T]
[b6]; Marks, Peter (FDA/CBER) [b6]

Subject: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Colleagues,

As the COVID-19 pandemic rages on in many parts of the world, it is absolutely urgent to obtain rigorous data on possible therapeutic interventions that could save lives. Convalescent plasma is one of the more promising interventions, but still lacks rigorous evidence from well-powered randomized controlled trials, though a number of such trials are underway. Janet Woodcock (who leads the therapeutics workstream for Operation Warp Speed) and I are interested in convening all of the groups engaged in such RCTs, to see if there might be a way to accelerate progress – both for individual trials that might be sped up, or by well-designed meta-analyses.

Considering the importance of the issue, convening this group for a real time conversation is urgent. Accordingly, I am inviting you to join a **90-minute virtual meeting tomorrow, Tuesday July 28, starting at 11 AM EDT**. Zoom links will be sent shortly.

I would like each group to come prepared to give a quick synopsis of the status of your trial efforts – to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results. In some instances

(such as the C3PO study) I have invited more than one investigator working on a collaborative trial, and I would appreciate the PIs agreeing about who is the best position to summarize that trial.

I apologize in advance for the ridiculously short notice! But as in all things COVID, the usual timetables for organizing meetings have gone out the window.

Please respond to Ashley Parker [b6] about your willingness to join the meeting.

Many thanks, Francis

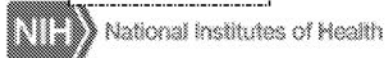
Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 7/27/2020 11:49:37 PM
To: Shmuel Shoham [b6]; Dan Hanley [b6]
CC: David Sullivan [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Shmuel,

Received – thank you.
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



From: Shmuel Shoham [b6]
Sent: Monday, July 27, 2020 6:48 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Dan Hanley [b6]
Cc: David Sullivan [b6]
Subject: Re: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Dr. Parker,

Attached is the slide for the post exposure prophylaxis study.

Thank you for organizing everything and working so hard to find treatments for this virus.

-Shmuel

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 27, 2020 4:02 PM
To: Dan Hanley
Cc: David Sullivan; Shmuel Shoham
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Dan,

Thank you for the information. I will standby for the 2 slides to be presented by Dan and Shmuel and the completed excel spreadsheet.

Thanks,

Ashley

Ashley Parker, Ph.D.

Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

Office of the Director | National Institutes of Health

Tel: [b6]



From: Dan Hanley <[b6]>
Sent: Monday, July 27, 2020 3:33 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: David Sullivan <[b6]> Shmuel Shoham <[b6]>
Subject: Re: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Ashely

We will get one slide to you at the end of the day. We have two studies. Dr Shoham will give the brig update for his study of exposed COVID negative patients CSSC -001 and Dr Sullivan CSSC - 004 will present his outpatient COVID positive study. I will listen. Thanks sending the invite so I can listen .

We will complete the spread sheet

Sent from my iPhone

Dan Hanley, MD

Johns Hopkins University

APAR0000011135

b6

On Jul 27, 2020, at 2:18 PM, Parker, Ashley (NIH/OD) [E] b6 wrote:

Dear Dan,

Apologies you were not included in the email thread below. Mike Kurilla requested that I forward you the invitation below.

If available, we are asking for one representative from each CP trial to present a single slide (5-min) with the requested details Dr. Collins provided below (to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results.

We are also collating this information into the attached spreadsheet – we need the highlighted information to be completed.

Please let me know if you are available to attend and who will be responsible for presenting a single slide for the CSSC trial and completing the remaining information in the attached spreadsheet to be included for discussion tomorrow. Apologies for the quick turnaround – could we have the single slide and completed highlighted information by **COB today**?

I'm including Dan and Shmuel as well – Shmuel has already confirmed attendance.

Thanks,

Ashley

Ashley Parker, Ph.D.

Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

Office of the Director | National Institutes of Health

Tel: [b6]

<image001.png>

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Monday, July 27, 2020 6:54 AM

To: [b6]

[b6]

[b6]; Ralph Sacco [b6]

[b6]

Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]

[b6]; Anderson, James (NIH/OD) [E] [b6];

Austin, Christopher (NIH/NCATS) [E] [b6]; Lane, Cliff (NIH/NIAID) [E]

[b6]; Fauci, Anthony (NIH/NIAID) [E] [b6]; Gibbons, Gary

(NIH/NHLBI) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E]

[b6]; Rutter, Joni (NIH/NCATS) [E] [b6]; Kurilla, Michael

(NIH/NCATS) [E] [b6]; Woodcock, Janet (FDA/CDER)

[b6]; Disbrow, Gary (OS/ASPR/BARDA) [b6]

Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6];

Marks, Peter (FDA/CBER) [b6]

Subject: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Colleagues,

As the COVID-19 pandemic rages on in many parts of the world, it is absolutely urgent to obtain rigorous data on possible therapeutic interventions that could save lives. Convalescent plasma is one of the more promising interventions, but still lacks rigorous evidence from well-powered randomized controlled trials, though a number of such trials are underway. Janet Woodcock (who leads the therapeutics workstream for Operation Warp Speed) and I are interested in convening all of the groups engaged in such RCTs, to see if there might be a way to accelerate progress – both for individual trials that might be sped up, or by well-designed meta-analyses.

Considering the importance of the issue, convening this group for a real time conversation is urgent. Accordingly, I am inviting you to join a **90-minute virtual meeting tomorrow, Tuesday July 28, starting at 11 AM EDT**. Zoom links will be sent shortly.

I would like each group to come prepared to give a quick synopsis of the status of your trial efforts – to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results. In some instances (such as the C3PO study) I have invited more than one investigator working on a collaborative trial, and I would appreciate the PIs agreeing about who is the best position to summarize that trial.

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Please respond to Ashley Parker [b6] about your willingness to join the meeting.

Many thanks, Francis

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health

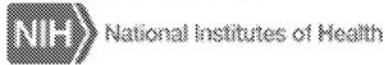
<JHU CP RCT 072720.xlsx>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 7/27/2020 11:48:39 PM
To: David Sullivan [b6]; Dan Hanley [b6]; Shmuel Shoham [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear David,

Received – thank you.
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: 301-594-7743



From: David Sullivan [b6]
Sent: Monday, July 27, 2020 4:50 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Dan Hanley [b6]; Shmuel Shoham [b6]
Subject: Re: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Ashley,
We have filled out the table.
David Sullivan will present the Early treatment protocol Convalescent Plasma to Limit SARS-CoV-2 NCT04373460
Shmuel Shoham will present the Infection prevention (prophylaxis) protocol Convalescent Plasma to Stem Coronavirus NCT04323800
Our single slide for each separate study will follow.
Dan Hanley will listen as part of our executive committee and guest of Mike Kurilla.
Thanks you
David Sullivan

From: "Parker, Ashley (NIH/OD) [E]" [b6]
Date: Monday, July 27, 2020 at 2:18 PM
To: Dan Hanley [b6], David Sullivan [b6], Shmuel Shoham [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

External Email - Use Caution

Dear Dan,

APAR0000011139

Apologies you were not included in the email thread below. Mike Kurilla requested that I forward you the invitation below.

If available, we are asking for one representative from each CP trial to present a single slide (5-min) with the requested details Dr. Collins provided below (to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results.

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I'm including Dan and Shmuel as well – Shmuel has already confirmed attendance.

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health

Tel: [REDACTED]



National Institutes of Health

From: Collins, Francis (NIH/OD) [E] [REDACTED]

Sent: Monday, July 27, 2020 6:54 AM

To: [REDACTED]
[REDACTED] Ralph Sacco

b6

Cc: Parker, Ashley (NIH/OD) [E] [REDACTED]; Tabak, Lawrence (NIH/OD) [E] [REDACTED]
Anderson, James (NIH/OD) [E] [REDACTED]; Austin, Christopher (NIH/NCATS) [E]
[REDACTED]; Lane, Cliff (NIH/NIAID) [E] [REDACTED]; Fauci, Anthony (NIH/NIAID) [E]
[REDACTED]; Gibbons, Gary (NIH/NHLBI) [E] [REDACTED]; Patterson, Amy (NIH/NHLBI) [E]
[REDACTED]; Rutter, Joni (NIH/NCATS) [E] [REDACTED]; Kurilla, Michael (NIH/NCATS) [E]
[REDACTED]; Woodcock, Janet (FDA/CDER) [REDACTED]; Disbrow, Gary
(OS/ASPR/BARDA) [REDACTED]; Freire, Maria (FNIH) [T] [REDACTED]; Wholley, David (FNIH) [T]
[REDACTED]; Marks, Peter (FDA/CBER) [REDACTED]

Subject: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Colleagues,

As the COVID-19 pandemic rages on in many parts of the world, it is absolutely urgent to obtain rigorous data on possible therapeutic interventions that could save lives. Convalescent plasma is one of the more promising interventions, but still lacks rigorous evidence from well-powered randomized controlled trials, though a number of such trials are underway. Janet Woodcock (who leads the therapeutics workstream for Operation Warp Speed) and I are interested in convening all of the groups engaged in such RCTs, to see if there might be a way to accelerate progress – both for individual trials that might be sped up, or by well-designed meta-analyses.

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Please respond to Ashley Parker [b6] about your willingness to join the meeting.

Many thanks, Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 7/28/2020 1:12:15 PM
To: Pulley, Jill [b6]; Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
CC: Rice, Todd [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Thank you, Jill.
Ashley

From: Pulley, Jill [b6]
Sent: Tuesday, July 28, 2020 9:11 AM
To: Parker, Ashley (NIH/OD) [E] <ashley.parker@nih.gov>; Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
Cc: Rice, Todd [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

No, we will still need to present our overall synopsis slide of our study.
The timeline 'modeling' was more of a backup to you, and perhaps to the group, if needed.
Thank you, and sorry for any confusion,
Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, July 28, 2020 8:04 AM
To: Pulley, Jill [b6]; Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
Cc: Rice, Todd [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Jill,

A single slide can be presented. Would you prefer to replace the current slide?

Thanks,
Ashley

From: Pulley, Jill [b6]
Sent: Tuesday, July 28, 2020 9:00 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
Cc: Rice, Todd [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Ashley,

At the risk of sending something that wasn't requested, we wanted to share that in planning a multi-site trial, our group has done modeling around how to produce results quickly. We have spoken to trial leadership across many sites to vet assumptions and expectations, are tracking geographic surges, and have assessed the tradeoff between cost and time. A synopsis of that tradeoff is attached, in case relevant for discussions.
Sorry for additional slide, and thank you so much for organizing,
Jill

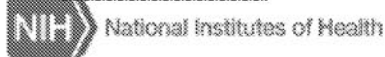
From: Parker, Ashley (NIH/OD) [E] <[b6]>
Sent: Monday, July 27, 2020 5:38 PM
To: Pulley, Jill <[b6]>; Jacobs, Chenoa <[b6]>; Bernard, Gordon
<[b6]>
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Hi Jill,

We received the additional materials as well – we greatly appreciate it and look forward to Dr. Bernard's presentation.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



From: Pulley, Jill <[b6]>
Sent: Monday, July 27, 2020 5:02 PM
To: Parker, Ashley (NIH/OD) [E] <[b6]>; Jacobs, Chenoa <[b6]>; Bernard, Gordon
<[b6]>
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Ashley,
Supplemental materials attached.
Happy to provide anything further!
Jill

From: Parker, Ashley (NIH/OD) [E] <[b6]>
Sent: Monday, July 27, 2020 2:36 PM
To: Pulley, Jill <[b6]>; Jacobs, Chenoa <[b6]>; Bernard, Gordon
<[b6]>
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Jill,

Thank you for confirming. Could you please send me the name and email of the additional PI and our team will be sending the invites shortly.

The single slide and completed excel file should be sufficient however feel free to submit a few additional back pocket slides is preferred.

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health

From: Pulley, Jill [b6]
Sent: Monday, July 27, 2020 2:59 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Ashley,
I will attend, Dr. Bernard will present. We also have another individual (Study PI) attending, would it be acceptable for us to forward the invite?
We will have our one slide summary to you shortly. Would a set of back up slides with further detailed information be helpful?
We will fill out the excel row ASAP in the file you provided.
Thank you so much! Looking forward to the call tomorrow.
Jill

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 27, 2020 1:33 PM
To: Jacobs, Chenoa [b6]; Bernard, Gordon [b6]
Cc: Pulley, Jill [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Chenoa and Dr. Gordon,

Thank you for confirming attendance for tomorrow's meeting. Will Jill plan to attend as well?

We are asking for one representative from each CP trial to present a single slide (5-min) with the requested details Dr. Collins provided below (to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results.

We are also collating this information into the attached spreadsheet if available.

Dr. Gordon are you interested in presenting a single slide and completing the information in the attached spreadsheet to be included for discussion tomorrow? If so, please send this information by **COB today** and we apologize for the quick turnaround.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]

From: Jacobs, Chenoa <[REDACTED] b6>
Sent: Monday, July 27, 2020 10:30 AM
To: Parker, Ashley (NIH/OD) [E]: [REDACTED] b6
Subject: FW: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Hello Ashley,
Dr. Gordon Bernard WILL be able to attend tomorrow's meeting.
Thanks,

Chenoa T. Jacobs
Executive Assistant to
Gordon R. Bernard, M.D.
Executive Vice President for Research
Director, Vanderbilt Institute for Clinical & Translational Research
Medical Center North, T-1208 | Nashville, TN 37232-2650

[REDACTED] b6
[REDACTED] b6 direct | 615.343-4479 – fax

VANDERBILT UNIVERSITY
MEDICAL CENTER

From: Pulley, Jill [REDACTED] b6
Sent: Monday, July 27, 2020 7:50 AM
To: Bernard, Gordon [REDACTED] b6
Cc: Jacobs, Chenoa [REDACTED] b6
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Noting this
Please respond to Ashley Parker [REDACTED] b6 about your willingness to join the meeting.

Please respond

From: Bernard, Gordon [REDACTED] b6
Sent: Monday, July 27, 2020 7:22 AM
To: Rice, Todd <[REDACTED] b6>; Pulley, Jill <[REDACTED] b6>; Self, Wesley H <[REDACTED] b6>;
Lindsell, Christopher John <[REDACTED] b6>; Rhoads, Jillian P <[REDACTED] b6>
Subject: Fwd: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Very interesting development!

Gordon Bernard sent from my iPhone

Begin forwarded message:

From: "Collins, Francis (NIH/OD) [E]" [REDACTED] b6
Date: July 27, 2020 at 5:54:08 AM CDT
To: [REDACTED] b6

[REDACTED] b6
[REDACTED] b6 Ralph Sacco
[REDACTED] b6

b6
Cc: "Parker, Ashley (NIH/OD) [E]" b6, "Tabak, Lawrence (NIH/OD) [E]"
b6, "Anderson, James (NIH/OD) [E]" b6, "Austin,
Christopher (NIH/NCATS) [E]" b6, "Lane, Cliff (NIH/NIAID) [E]"
b6, "Fauci, Anthony (NIH/NIAID) [E]" b6, "Gibbons, Gary
(NIH/NHLBI) [E]" b6, "Patterson, Amy (NIH/NHLBI) [E]" b6
"Rutter, Joni (NIH/NCATS) [E]" b6, "Kurilla, Michael (NIH/NCATS) [E]"
b6, "Woodcock, Janet (FDA/CDER)" b6, "Disbrow,
Gary (OS/ASPR/BARDA)" b6, "Freire, Maria (FNIH) [T]" b6
"Wholley, David (FNIH) [T]" b6, "Marks, Peter (FDA/CBER)"
b6

Subject: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Colleagues,

As the COVID-19 pandemic rages on in many parts of the world, it is absolutely urgent to obtain rigorous data on possible therapeutic interventions that could save lives. Convalescent plasma is one of the more promising interventions, but still lacks rigorous evidence from well-powered randomized controlled trials, though a number of such trials are underway. Janet Woodcock (who leads the therapeutics workstream for Operation Warp Speed) and I are interested in convening all of the groups engaged in such RCTs, to see if there might be a way to accelerate progress – both for individual trials that might be sped up, or by well-designed meta-analyses.

Considering the importance of the issue, convening this group for a real time conversation is urgent. Accordingly, I am inviting you to join a **90-minute virtual meeting tomorrow, Tuesday July 28, starting at 11 AM EDT**. Zoom links will be sent shortly.

I would like each group to come prepared to give a quick synopsis of the status of your trial efforts – to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results. In some instances (such as the C3PO study) I have invited more than one investigator working on a collaborative trial, and I would appreciate the PIs agreeing about who is the best position to summarize that trial.

I apologize in advance for the ridiculously short notice! But as in all things COVID, the usual timetables for organizing meetings have gone out the window.

Please respond to Ashley Parker b6 about your willingness to join the meeting.

Many thanks, Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

[WARNING : This email came from an external source. Please treat this message with additional caution.]

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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/24/2021 8:25:05 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: List of all the members for all the WG and subgroups and subteams

OK, thanks.

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, February 24, 2021 2:57 PM
To: Parker, Ashley (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6]
Subject: FW: List of all the members for all the WG and subgroups and subteams

Another set of names.

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health

[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852



From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Wednesday, February 24, 2021 2:44 PM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: FW: List of all the members for all the WG and subgroups and subteams

Another set of names. Wow, this is a lot of people.

From: Hawk, Harrison <hhawk@deloitte.com>
Sent: Wednesday, February 24, 2021 2:29 PM
To: Menetski, Joseph (FNIH) [T] [b6] Connelly, Sarah <sconnelly@deloitte.com>
Subject: RE: List of all the members for all the WG and subgroups and subteams

Hi Joe,

I'm following up with a separate spreadsheet that lists all of the Preclinical WG & Subgroup members. I followed the same format as the one we used for the TRACE groups. Let me know if you can suggest modifications.

Best regards,

APAR0000011217

Harrison

From: Hawk, Harrison
Sent: Tuesday, February 23, 2021 7:19 PM
To: Menetski, Joseph (FNIH) [T] [b6]; Connelly, Sarah <sconnelly@deloitte.com>
Subject: RE: List of all the members for all the WG and subgroups and subteams

Hi Joe,

Please find the complete list of ACTIV TRACE WG & Subgroup members. There is a main sheet that has the full list of WG members, and separate tabs for each subgroup. I am working to put together the same style spreadsheet for the full Preclinical WG. Please let me know if you have any feedback.

Best,
Harrison

From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Tuesday, February 23, 2021 3:16 PM
To: Hawk, Harrison <hhawk@deloitte.com>; Connelly, Sarah <sconnelly@deloitte.com>
Subject: [EXT] List of all the members for all the WG and subgroups and subteams

Dear Harrison and Sarah,

Do we have the lists done? I just got a request for this from NIH OD.

Joe

Joseph P. Menetski, Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
[b6] fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



This message (including any attachments) contains confidential information intended for a specific individual and purpose, and is protected by law. If you are not the intended recipient, you should delete this message and any disclosure, copying, or distribution of this message, or the taking of any action based on it, by you is strictly prohibited.

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APAR0000011217

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 7/27/2020 6:33:19 PM
To: Jacobs, Chenoa [b6] Bernard, Gordon [b6]
CC: Pulley, Jill [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly
Attachments: FW: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly; Vanderbilt CP RCT 072720.xlsx

Dear Chenoa and Dr. Gordon,

Thank you for confirming attendance for tomorrow's meeting. Will Jill plan to attend as well?

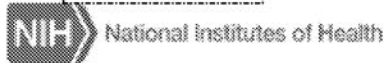
We are asking for one representative from each CP trial to present a single slide (5-min) with the requested details Dr. Collins provided below (to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results.

We are also collating this information into the attached spreadsheet if available.

Dr. Gordon are you interested in presenting a single slide and completing the information in the attached spreadsheet to be included for discussion tomorrow? If so, please send this information by **COB today** and we apologize for the quick turnaround.

Thank you,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



From: Jacobs, Chenoa [b6]
Sent: Monday, July 27, 2020 10:30 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Hello Ashley,
Dr. Gordon Bernard WILL be able to attend tomorrow's meeting.
Thanks,

Chenoa T. Jacobs
Executive Assistant to
Gordon R. Bernard, M.D.
Executive Vice President for Research
Director, Vanderbilt Institute for Clinical & Translational Research
Medical Center North, T-1208 | Nashville, TN 37232-2650

[b6]
[b6] direct|615.343-4479 – fax

APAR0000011234

From: Pulley, Jill <b6>
Sent: Monday, July 27, 2020 7:50 AM
To: Bernard, Gordon
Cc: Jacobs, Chenoa <b6>
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Noting this

Please respond to Ashley Parker <b6> about your willingness to join the meeting.

Please respond

From: Bernard, Gordon <b6>
Sent: Monday, July 27, 2020 7:22 AM
To: Rice, Todd <b6> Pulley, Jill <b6> Self, Wesley H <b6>
Lindsell, Christopher John <b6>; Rhoads, Jillian P <b6>
Subject: Fwd: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Very interesting development!

Gordon Bernard sent from my iPhone

Begin forwarded message:

From: "Collins, Francis (NIH/OD) [E]" <b6>
Date: July 27, 2020 at 5:54:08 AM CDT
To: <b6>
<b6>
<b6> Ralph Sacco
<b6>
Cc: "Parker, Ashley (NIH/OD) [E]" <b6> "Tabak, Lawrence (NIH/OD) [E]"
<b6> "Anderson, James (NIH/OD) [E]" <b6> ">, "Austin,
Christopher (NIH/NCATS) [E]" <b6> "Lane, Cliff (NIH/NIAID) [E]"
<b6> "Fauci, Anthony (NIH/NIAID) [E]" <b6> "Gibbons, Gary
(NIH/NHLBI) [E]" <b6> "Patterson, Amy (NIH/NHLBI) [E]" <b6>
"Rutter, Joni (NIH/NCATS) [E]" <b6> "Kurilla, Michael (NIH/NCATS) [E]"
<b6> "Woodcock, Janet (FDA/CDER)" <b6> "Disbrow,
Gary (OS/ASPR/BARDA)" <b6> "Freire, Maria (FNIH) [T]" <b6>
"Wholley, David (FNIH) [T]" <b6> "Marks, Peter (FDA/CBER)"
<b6>

Subject: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Colleagues,

As the COVID-19 pandemic rages on in many parts of the world, it is absolutely urgent to obtain rigorous data on possible therapeutic interventions that could save lives. Convalescent plasma is one of the more promising interventions, but still lacks rigorous evidence from well-powered randomized controlled trials, though a number of such trials are underway. Janet Woodcock (who leads the therapeutics workstream for Operation Warp Speed) and I are interested in convening all of the groups engaged in such RCTs, to see if there might be a way to accelerate progress – both for individual trials that might be sped up, or by well-designed meta-analyses.

Considering the importance of the issue, convening this group for a real time conversation is urgent. Accordingly, I am inviting you to join a **90-minute virtual meeting tomorrow, Tuesday July 28, starting at 11 AM EDT**. Zoom links will be sent shortly.

I would like each group to come prepared to give a quick synopsis of the status of your trial efforts – to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results. In some instances (such as the C3PO study) I have invited more than one investigator working on a collaborative trial, and I would appreciate the PIs agreeing about who is the best position to summarize that trial.

I apologize in advance for the ridiculously short notice! But as in all things COVID, the usual timetables for organizing meetings have gone out the window.

Please respond to Ashley Parker (b6) about your willingness to join the meeting.

Many thanks, Francis

Francis S. Collins, M.D., Ph.D.

Director, National Institutes of Health

[WARNING : This email came from an external source. Please treat this message with additional caution.]

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 7/27/2020 6:14:38 PM
To: [b6] Shmuel Shoham [b6]
Subject: Re: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly
Attachments: JHU CP RCT 072720.xlsx

Dear Dan,

Apologies you were not included in the email thread below. Mike Kurilla requested that I forward you the invitation below.

If available, we are asking for one representative from each CP trial to present a single slide (5-min) with the requested details Dr. Collins provided below (to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results.

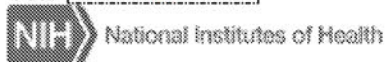
We are also collating this information into the attached spreadsheet – we need the highlighted information to be completed.

Please let me know if you are available to attend and who will be responsible for presenting a single slide for the CSSC trial and completing the remaining information in the attached spreadsheet to be included for discussion tomorrow. Apologies for the quick turnaround – could we have the single slide and completed highlighted information by **COB today**?

I'm including Dan and Shmuel as well – Shmuel has already confirmed attendance.

Thanks,
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Monday, July 27, 2020 6:54 AM

To: [b6]
[b6] Ralph Sacco

[b6]

Cc: Parker, Ashley (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6];
Anderson, James (NIH/OD) [E] [b6]; Austin, Christopher (NIH/NCATS) [E]

[b6] Lane, Cliff (NIH/NIAID) [E] [b6]; Fauci, Anthony (NIH/NIAID) [E]
Gibbons, Gary (NIH/NHLBI) [E] [b6]; Patterson, Amy (NIH/NHLBI) [E]

[b6] Rutter, Joni (NIH/NCATS) [E] [b6]; Kurilla, Michael (NIH/NCATS) [E]
Woodcock, Janet (FDA/CDER) [b6] Disbrow, Gary

(OS/ASPR/BARDA) [b6] Freire, Maria (FNIH) [T] [b6] Wholley, David (FNIH) [T]
<dwholley@fnih.org>; Marks, Peter (FDA/CBER) [b6]

Subject: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Colleagues,

As the COVID-19 pandemic rages on in many parts of the world, it is absolutely urgent to obtain rigorous data on possible therapeutic interventions that could save lives. Convalescent plasma is one of the more promising interventions, but still lacks rigorous evidence from well-powered randomized controlled trials, though a number of such trials are underway. Janet Woodcock (who leads the therapeutics workstream for Operation Warp Speed) and I are interested in convening all of the groups engaged in such RCTs, to see if there might be a way to accelerate progress – both for individual trials that might be sped up, or by well-designed meta-analyses.

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Please respond to Ashley Parker [b6] about your willingness to join the meeting.

Many thanks, Francis

Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/14/2020 1:42:17 AM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wood, Gretchen (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=549f390b39d044a8b5d1e0e1a8f76c1f-woodgs]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

Yes, the gift of NOT adding another meeting!

On 5/13/20, 9:28 PM, "Wholley, David (FNIH) [T]" [b6] wrote:

ok, good thanks.

-----Original Message-----

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 9:26 PM
To: Wholley, David (FNIH) [T] [b6]; Wood, Gretchen (NIH/OD) [E] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

David
Thanks; this is our regular meeting with ICDs - so no.
Larry

On 5/13/20, 8:46 PM, "Wholley, David (FNIH) [T]" [b6] wrote:

You are not expecting me to be on this call are you? I do not have an invitation on my calendar. Happy not to be--just checking.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 8:30 PM
To: Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Gladman, Jordan (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

I'd like to push the easy button. Jordan, you're it!

-----Original Message-----

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 8:29 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Gladman, Jordan (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

It may be easier for you to have Jordan control. Otherwise you need to put on your screen top and we can make you "presenter". Which do you prefer?
Larry

On 5/13/20, 8:28 PM, "Collins, Francis (NIH/OD) [E]" [b6] wrote:

This set looks good. Please delete the extra slides starting with the black side, and then load into sharepoint and queue up for tomorrow. Will I be able to share screen and control the slide changes, or will I need to ask Jordan for help?

Tara, I will count on you to explain the last two slides on the portal.

Francis

-----Original Message-----

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 7:08 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E]
[b6]; George, Jill (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
[b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Francis,

Please see the slide set with additions from today's vaccine working group meeting (with input from Mike Santos, please see notes). With many thanks to Tara and Jill, please also see the RADx and COVID portal slides for possible inclusion.

Thanks,
Ashley

I-----Original Message-----

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 3:33 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
[b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; wholley, David (FNIH) [T]
[b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Francis,

We've asked for the slides NIAID presented on the draft plan to the vaccine working today and will provide a single summary slide.

Thanks,
Ashley

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Sent: Wednesday, May 13, 2020 1:28 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
[b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; wholley, David (FNIH) [T]
[b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

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FC

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From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 11:25 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
[b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; wholley, David (FNIH) [T]
[b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

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Please see the attached revised set for tomorrow's ICD meeting based on your notes below and discussions at the ACTIV EC meeting this morning. There are 9 core presentation slides and I've moved the challenges/recommended actions (slides 10-11) to the end for discussion with the group.

As mentioned on our call yesterday, I think Jim would like to briefly discuss the NHP strategy/use of resources (slide 5) if time permits -- looping in Jim to confirm.

Standing by if anything else is needed.

Thanks,
Ashley

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To: Collins, Francis (NIH/OD) [E]

Cc: Tabak, Lawrence (NIH/OD) [E]

b6

; Wholley, David (FNIH) [T]

Subject: Re: Materials: ICD Meeting Committee 5/14/2020

Hi Francis,

Great plan - we will adjust accordingly and standby for additional edits that may come out of the executive committee meeting.

Thanks,
Ashley

> On May 13, 2020, at 7:03 AM, Collins, Francis (NIH/OD) [E] b6 wrote:

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> Hi Ashley,

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> Thanks for putting this slide set together. I'd like to see what happens in the Exec Comm/WG meeting this morning, and then we can finalize. I will want to move many of the slides to back up -- as we only have a half hour for the discussion and the presentation part shouldn't be more than 10 minutes -- the main goal is to inspire discussion. You can take out the discussion place holder slides - I think I will try to go through the whole presentation before opening it up to questions, or we might not get to the vaccines.

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> Francis

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> From: Parker, Ashley (NIH/OD) [E] b6

> Sent: Tuesday, May 12, 2020 7:04 PM

> To: Collins, Francis (NIH/OD) [E]

b6

> Cc: Tabak, Lawrence (NIH/OD) [E]

> David (FNIH) [T] b6

> Subject: RE: Materials: ICD Meeting Committee 5/14/2020

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> Thank you,

> Ashley

>

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> From: Wholley, David (FNIH) [T] b6

> Sent: Tuesday, May 12, 2020 7:14 AM

> To: Parker, Ashley (NIH/OD) [E] b6

> Francis (NIH/OD) [E] b6

> Cc: Tabak, Lawrence (NIH/OD) [E] b6

> Subject: RE: Materials: ICD Meeting Committee 5/14/2020

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> Send them the Science article too

>

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> Cc: Wholley, David (FNIH) [T] b6

> Tabak, Lawrence (NIH/OD) [E] b6

> Subject: Re: Materials: ICD Meeting Committee 5/14/2020

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> Thanks,
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>> Sent: Monday, May 11, 2020 10:22 PM
>> To: ICDDIR-L@LIST.NIH.GOV
>> Cc: IC Directors Meeting <ICDirectorsMeeting@od.nih.gov>
>> Subject: Materials: ICD Meeting Committee 5/14/2020
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>> Colleagues,
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>> We will have a IC Directors meeting Thursday, May 14, 8:30 AM to 10:00 AM by WebEx.
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>> Materials are attached.
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>> * Agenda
>> * AoU Researcher Workbench
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>> Materials are also posted to the ICD SharePoint site:
>> <https://sps.od.nih.gov/ICdirector/default.aspx>
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>> Larry
>>
>> ---
>> JOIN WEBEX MEETING
>> <https://nih.webex.com/nih/> [b6]
>> a Meeting number (access code): [b6] Meeting password:
>> [b6]
>>
>>
>> * When choosing your audio connection, select either the Call Me, I will Call In*, Call
Using Computer (Desktop), or Use Internet for audio (Mobile) feature to ensure your name appears in the
participant list.
>> * *If you chose the I will Call In dial-in option, please be sure to enter your
attendee ID number that will be displayed once you are logged in from your computer in an effort to
identify each participant.
>> * Phone dial-in should only be used as a last resort means if the WebEx site, desktop or
mobile app cannot be utilized. If using a phone, when your time to speak is open, use *6 to unmute
yourself. If you use this method please email Jordan Gladman with your phone number.
>>
>> JOIN BY PHONE
>> [b6] Call-in number (US/Canada)
>>
>> Access code: [b6]
>>
>>
>> <2020-05-14_IC Directors Agenda.docx> <IC Directors Presentation
>> 05.14.20 - long - Read-Only.pptx> <IC Directors Presentation
>> 05.14.20 - short[1] - Read-Only.pptx>

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/14/2020 1:26:12 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

Yes I can.
Thanks

On 5/13/20, 8:54 PM, "Parker, Ashley (NIH/OD) [E]" [b6] wrote:

Hi Jordan,

Please see attached. Larry, can you open this file?

Thanks,
Ashley

-----Original Message-----

From: Gladman, Jordan (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 8:50 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] <georgejil@od.nih.gov>; Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Sounds good. I don't have a copy of the slides so please send me the final presentation before the meeting tomorrow and I'll have everything ready for you.

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 8:30 PM
To: Tabak, Lawrence (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Gladman, Jordan (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

I'd like to push the easy button. Jordan, you're it!

-----Original Message-----

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 8:29 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Cc: George, Jill (NIH/OD) [E] <georgejil@od.nih.gov>; Anderson, James (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Gladman, Jordan (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

It may be easier for you to have Jordan control. Otherwise you need to put on your screen top and we can make you "presenter". Which do you prefer?
Larry

On 5/13/20, 8:28 PM, "Collins, Francis (NIH/OD) [E]" [b6] wrote:

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[b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

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Thanks,
Ashley

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>> Sent: Monday, May 11, 2020 10:22 PM
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>> Thanks,
>> Larry
>>
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>> JOIN WEBEX MEETING
>> <https://nih.webex.com/nih/> [b6]
>> a Meeting number (access code): [b6] Meeting password:
>> [b6]
>>
>>
>> * When choosing your audio connection, select either the Call Me, I Will Call In*, Call Using Computer (Desktop), or Use Internet for audio (Mobile) feature to ensure your name appears in the participant list.
>> * *If you chose the I Will Call In dial-in option, please be sure to enter your attendee ID number that will be displayed once you are logged in from your computer in an effort to identify each participant.
>> * Phone dial-in should only be used as a last resort means if the WebEx site, desktop or mobile app cannot be utilized. If using a phone, when your time to speak is open, use *6 to unmute yourself. If you use this method please email Jordan Gladman with your phone number.
>>
>> JOIN BY PHONE
>> [b6] Call-in number (US/Canada)
>>
>> Access code: [b6]
>>
>>
>> <2020-05-14_IC Directors Agenda.docx> <IC Directors Presentation
>> 05.14.20 - long - Read-Only.pptx> <IC Directors Presentation
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From: Schwetz, Tara (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B1DA1E9650D44FA9A9E2D94F24B5035-SCHWETZTA]
Sent: 5/14/2020 12:51:22 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; George, Jill (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f90bffb4b3a2464382adc29b127aed4e-georgejil]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Gladman, Jordan (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eb38a598f96f488299a655a7312138fd-gladmanjt]
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Sounds good!

Tara A. Schwetz, PhD
National Institutes of Health

b6

Sent from my iPhone

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Sent: Tuesday, May 12, 2020 7:04 PM

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Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley,
David (FNIH) [T] [b6]; George, Jill (NIH/OD) [E]
[b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Francis,

Please see attached draft ACTIV slides for the ICD meeting on Thursday. With thanks to Jill for formatting.

I've included place holder slides for discussion in between the working group topics in case you want to stop and take questions/discuss -- we can delete these if you prefer to hold discussions for the end.

Thank you,
Ashley

-----Original Message-----

From: Wholley, David (FNIH) [T] [b6]
Sent: Tuesday, May 12, 2020 7:14 AM
To: Parker, Ashley (NIH/OD) [E] [b6]; Collins,
Francis (NIH/OD) [E] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Send them the Science article too

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From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 6:39 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]; Tabak, Lawrence
(NIH/OD) [E] [b6]
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

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Are there other items, anything else specifically you would like to discuss with the ICDs about ACTIV? Mention of JAMA article but this doesn't need a slide, right?

Happy to help.

Thanks,
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From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 10:22 PM
To: ICDDIR-L@LIST.NIH.GOV
Cc: IC Directors Meeting <ICDirectorsMeeting@od.nih.gov>
Subject: Materials: ICD Meeting Committee 5/14/2020

Colleagues,

We will have a IC Directors meeting Thursday, May 14, 8:30 AM to 10:00 AM by WebEx.

Materials are attached.

* Agenda

* AoU Researcher Workbench

Materials are also posted to the ICD SharePoint site:

<https://sps.od.nih.gov/ICdirector/default.aspx>

Thanks,

Larry

JOIN WEBEX MEETING

<https://nih.webex.com/nih/> **b6**
1ff25724867

a Meeting number (access code): **b6** Meeting password:

b6

* When choosing your audio connection, select either the Call Me, I Will Call In*, Call Using Computer (Desktop), or Use Internet for audio (Mobile) feature to ensure your name appears in the participant list.

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JOIN BY PHONE

b6

Call-in number (US/Canada)

Access code: **b6**

<2020-05-14_IC Directors Agenda.docx> <IC Directors Presentation

05.14.20 - long - Read-Only.pptx> <IC Directors Presentation

05.14.20 - short[1] - Read-Only.pptx>

From: Tabak, Lawrence (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=02E22836B5FF4E9988E3770CFC7EE770-TABAKL]
Sent: 5/13/2020 11:49:38 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
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Subject: Re: Materials: ICD Meeting Committee 5/14/2020

Please resend; the file was corrupted.

On 5/13/20, 7:10 PM, "Parker, Ashley (NIH/OD) [E]" [b6] wrote:

Hi Francis,

Please see the slide set with additions from today's vaccine working group meeting (with input from Mike Santos, please see notes). With many thanks to Tara and Jill, please also see the RADx and COVID portal slides for possible inclusion.

Thanks,
Ashley

I-----Original Message-----

From: Parker, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 3:33 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Anderson, James (NIH/OD) [E]
[b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T]
[b6]; George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Hi Francis,

We've asked for the slides NIAID presented on the draft plan to the vaccine working today and will provide a single summary slide.

Thanks,
Ashley

-----Original Message-----

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 1:28 PM
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[b6]
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As mentioned on our call yesterday, I think Jim would like to briefly discuss the NHP strategy/use of resources (slide 5) if time permits -- looping in Jim to confirm.

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Thanks,
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>> ---
>> JOIN WEBEX MEETING
>> <https://nih.webex.com/nih/j> [b6]
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>> [b6]
>>
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>>
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>>
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>> 05.14.20 - long - Read-Only.pptx> <IC Directors Presentation
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Sent: 5/13/2020 5:28:21 PM
To: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Anderson, James (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73143d1860bc42458be254ca21573b23-andersonjm]
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Subject: RE: Materials: ICD Meeting Committee 5/14/2020

still tinkering

-----Original Message-----

From: Tabak, Lawrence (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Sent: Wednesday, May 13, 2020 11:27 AM
To: Parker, Ashley (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>; Collins, Francis (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>; Anderson, James (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Cc: Wholley, David (FNIH) [T] <[REDACTED] b6 [REDACTED]>; George, Jill (NIH/OD) [E] <[REDACTED] b6 [REDACTED]>
Subject: Re: Materials: ICD Meeting Committee 5/14/2020

Please let me know if you want the slide deck circulated to ICDs, or just placed on SharePoint site.
Thanks
Larry

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Thanks, Jim!

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Sent: Wednesday, May 13, 2020 2:22 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E]
CC: Tabak, Lawrence (NIH/OD) [E] [b6]; wholley, David (FNIH) [T] [b6]
George, Jill (NIH/OD) [E] [b6]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

I want to add another perspective on the preclinical WG NHP efforts presented in the slides.

We are working closely with the Directors of the NIH(OD)-supported NPRCs. One of their Directors is on the Preclinical WG. By May 15 they were asked to propose a coordination process for them to respond to ACTIV priorities for studies using NHPs and facilities. It was suggested to them that one option could be creation of a coordinating center representing all 7 centers as the POC for ACTIV.

Not on the slides: NIAID maintains its own NHP facilities. Industry typically uses contracting breeding/research facilities. These resources remain semi-dark matter. More work is required to understand and coordinate studies conducted in this space with ACTIV.

Some ICDs think that ACTIV is claiming control of all NHP and for example, HIV and neuroscience is on hold. Not true, but the NPRC Directors know that in the short term ACTIV projects have top priority and all others will be reviewed relative to the needs for ACTIV.

If asked on May 14 I think it better to say we are aware that competing interests exist. We (ACTIV and the NPRCs) are working toward a solution that serves NIH-wide needs but puts COVID research first.

Jim

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> From: Parker, Ashley (NIH/OD) [E] [b6]
> Sent: Tuesday, May 12, 2020 7:04 PM
> To: Collins, Francis (NIH/OD) [E] [b6]
> Cc: Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; George, Jill (NIH/OD) [E] [b6]
> Subject: RE: Materials: ICD Meeting Committee 5/14/2020

> Hi Francis,

> Please see attached draft ACTIV slides for the ICD meeting on Thursday. With thanks to Jill for formatting.

> I've included place holder slides for discussion in between the working group topics in case you want to stop and take questions/discuss -- we can delete these if you prefer to hold discussions for the end.

> Thank you,
> Ashley

> -----Original Message-----

> From: Wholley, David (FNIH) [T] [b6]
> Sent: Tuesday, May 12, 2020 7:14 AM
> To: Parker, Ashley (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]
> Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
> Subject: RE: Materials: ICD Meeting Committee 5/14/2020

> Send them the science article too

>

> -----Original Message-----

> From: Parker, Ashley (NIH/OD) [E] {b6}

> Sent: Tuesday, May 12, 2020 6:39 AM

> To: Collins, Francis (NIH/OD) [E] {b6}

> Cc: Wholley, David (FNIH) [T] {b6}; Tabak, Lawrence (NIH/OD) [E] {b6}

> Subject: Re: Materials: ICD Meeting Committee 5/14/2020

>

> Hi Francis,

>

> Happy to work with David and his team to prepare slides. Is the plan to share any updates since the ACTIV leadership meeting last Wednesday? Honestly, not sure if there's a lot to report on the working groups at the moment however I defer to David.

>

> Are there other items, anything else specifically you would like to discuss with the ICDs about ACTIV? Mention of JAMA article but this doesn't need a slide, right?

>

> Happy to help.

>

> Thanks,

> Ashley

>

>

>> On May 12, 2020, at 6:27 AM, Collins, Francis (NIH/OD) [E] {b6} wrote:

>>

>> Hi Ashley and David,

>>

>> I'll need some help preparing a presentation on ACTIV for ICs on Thursday. Larry, should there also be a RADX update? Are you hearing from ICs about this?

>>

>> FC

>>

>> From: Tabak, Lawrence (NIH/OD) [E] {b6}

>> Sent: Monday, May 11, 2020 10:22 PM

>> To: ICDDIR-L@LIST.NIH.GOV

>> Cc: IC Directors Meeting <ICDirectorsMeeting@od.nih.gov>

>> Subject: Materials: ICD Meeting Committee 5/14/2020

>>

>> Colleagues,

>>

>> We will have a IC Directors meeting Thursday, May 14, 8:30 AM to 10:00 AM by WebEx.

>>

>> Materials are attached.

>>

>> * Agenda

>> * AoU Researcher Workbench

>>

>> Materials are also posted to the ICD SharePoint site:

>> <https://sps.od.nih.gov/ICdirector/default.aspx>

>>

>> Thanks,

>> Larry

>>

>> ---

>> JOIN WEBEX MEETING

>> <https://nih.webex.com/nih/> {b6}

>> a Meeting number (access code): {b6} Meeting password:

>> {b6}

>>

>>

>> * When choosing your audio connection, select either the Call Me, I Will Call In*, Call Using Computer (Desktop), or Use Internet for audio (Mobile) feature to ensure your name appears in the participant list.

>> * *If you chose the I Will Call In dial-in option, please be sure to enter your attendee ID number that will be displayed once you are logged in from your computer in an effort to identify each participant.

>> * Phone dial-in should only be used as a last resort means if the WebEx site, desktop or mobile app cannot be utilized. If using a phone, when your time to speak is open, use *6 to unmute yourself. If you use this method please email Jordan Gladman with your phone number.

>>

>> JOIN BY PHONE

>> {b6} Call-in number (US/Canada)

>>

>> Access code: {b6}

>>

>>


```
>> <2020-05-14_IC Directors Agenda.docx> <IC Directors Presentation
>> 05.14.20 - Long - Read-Only.pptx> <IC Directors Presentation
>> 05.14.20 - short[1] - Read-Only.pptx>
```

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/12/2020 11:12:50 AM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
Subject: RE: Materials: ICD Meeting Committee 5/14/2020

Sure, Francis. You should be able to simply pull slides from last week's leadership team meeting—I assume Kim Pelis and Jill George work on formatting per usual. Then just let me know if there is anything missing.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 6:27 AM
To: Parker, Ashley (NIH/OD) [E] [b6] Wholley, David (FNIH) [T] [b6]
Cc: Tabak, Lawrence (NIH/OD) [E] [b6]
Subject: FW: Materials: ICD Meeting Committee 5/14/2020

Hi Ashley and David,

I'll need some help preparing a presentation on ACTIV for ICs on Thursday. Larry, should there also be a RADx update? Are you hearing from ICs about this?

FC

From: Tabak, Lawrence (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 10:22 PM
To: ICDDIR-L@LIST.NIH.GOV
Cc: IC Directors Meeting <ICDirectorsMeeting@od.nih.gov>
Subject: Materials: ICD Meeting Committee 5/14/2020

Colleagues,

We will have a IC Directors meeting Thursday, May 14, 8:30 AM to 10:00 AM by WebEx.

Materials are attached.

- Agenda
- AoU Researcher Workbench

Materials are also posted to the ICD SharePoint site: <https://sps.od.nih.gov/ICdirector/default.aspx>

Thanks,
Larry

JOIN WEBEX MEETING

<https://nih.webex.com/nih/> [b6]
Meeting number (access code): [b6]
Meeting password: [b6]

- When choosing your audio connection, select either the **Call Me, I Will Call In***, **Call Using Computer (Desktop)**, or **Use Internet for audio (Mobile)** feature to ensure your name appears in the participant list.
 - ***If you chose the I Will Call In dial-in option, please be sure to enter your attendee ID number that will be displayed once you are logged in from your computer in an effort to identify each participant.**
- Phone dial-in should only be used as a last resort means if the WebEx site, desktop or mobile app cannot be utilized. If using a phone, when your time to speak is open, use *6 to unmute yourself. If you use this method please email Jordan Gladman with your phone number.

JOIN BY PHONE

Call-in number (US/Canada)

Access code:

From: Mensah, George (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=284D85649E634A0A91BB0B9AAC84846C-MENSAHGA]
Sent: 5/14/2020 6:25:33 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Abbey Meltzer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0b1348c6bb045bd8dda9301faea649a-3017066384.]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Dear Dr. Collins,

I am confirming that I agree to be listed on the web site as part of the ACTIV team.

My correct email address is [b6]

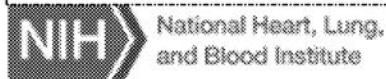
Thank you.

-George Mensah

George A. Mensah, MD, FACC, FAHA

Director, Center for Translation Research & Implementation Science
National Heart, Lung, and Blood Institute | National Institutes of Health
6705 Rockledge Drive | Suite 6070 | Bethesda | Maryland | 20892

[b6]



 twitter.com/NHLBI_Translate

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 1:17 PM
To: Weinmann, Gail (NIH/NHLBI) [E] [b6]; Mensah, George (NIH/NHLBI) [E]
[b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6] Melencio, Cheryl (FNIH) [T] [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

Hi Gail and George

I got a bounce back because somehow your e-mail addresses weren't quite correct in the original list, so I'm sending you this again.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] [b6]

Cc: Myles, Renate (NIH/OD) [E]; Meltzer, Abbey (FNIH) [T]; Wholley, David (FNIH) [T];

Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 5/14/2020 2:41:40 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Okay, thanks.

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:31 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Ok. ☺

You will need the updated slide 2 – we’ve made corrections in the JAMA piece for the official names of the WGs on the figure. They have changed over time but we’ve settled on these.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:29 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thanks; John is going to respond. We don’t put other company logos on our website.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:27 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Subject: FW: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

FYI.

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, May 14, 2020 10:26 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Slide 2: Updated name for Tx Clinical WG attached – I can share this with Renate once we have agreement to post these.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:18 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6];
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

How about these two?

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 8:03 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria
(FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6];
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis:

You mentioned that there are images in the presentations that we can use on the webpage, but those images seem very detailed and appear to contain confidential information to me. Would you let me know which particular image that you and David feel represents the overall program but doesn't give away too much information?

We're going to start building the page in draft today (not public).

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]

Sent: Wednesday, May 13, 2020 4:59 PM

To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria
(FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6];
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thanks, all. This is great information. I can add the items from Francis and David to the strategic comms plan and will look for comments from Abbey on the webpage/plan.

Will FNIH reach out to the EC/WG members to ask permission for listing them on the website? We'd love to get this page up this week, if possible.

Best,
Renate

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 4:38 PM
To: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good points.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 4:19 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis: two other things that are possible and not already on your list below 1) the position paper from the ACTIV Vaccines WG on the issue of doing human challenge trials for Vaccines which I would hope would be ready for release by some time next week 2) a monoclonal antibodies master protocol, timing TBD (since we just received the charge this morning)
David

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 4:07 PM
To: Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

b6

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi all,

I too want to say thanks to Renate for putting together this draft of the web page – it will be great to have something posted soon.

Building off of presentations to the Leadership Team/Exec Comm, we have a number of visuals that might be appropriate to include, and that would make the web site more pleasing to the eye.

I would be in favor of including the members of the working groups (it's a very impressive list) but only after asking their permission. It would also be good to designate the co-chairs of each of the Working Groups.

The Comms and Leg plan also looks good, though obviously there are uncertainties about the timing of various newsworthy events. In the not too distant future, I think we can imagine these developments:

- 1) Publication of the JAMA Viewpoint – Howard Bauchner has been moving this along at a very rapid pace, I wouldn't be surprised to see the publication emerge within the next week. Would that be a good moment to launch the web site?
- 2) Next week's planned summit, convened by ACTIV, on development of a master protocol(s) for monoclonal Abs – the meeting itself will be closed, but it might be possible to acknowledge that it's happening – as we did for the HEAL initiative a few times.
- 3) The launch of the anticoagulation four-arm trial, with leadership from NHLBI but under the ACTIV umbrella – I don't know exactly what the time table might be
- 4) The launch of the immunomodulator trial – which awaits working out the arrangements with the companies supplying the drugs, and then doing the match with the clinical trial networks that can make this work (through ACTT3)
- 5) The development and announcement of the harmonized master protocol for vaccines, with expectation that the first volunteers will be enrolled in the Ph II/III trials around July 1.

In the midst of all this, it looks like the US government is on the brink of announcing the joint HHS-DOD Manhattan Project 2, aka Operation Warp Speed, with Moncef Slaoui (former GSK) recruited to be the big kahuna, and a general from DoD as deputy. We will need to have materials ready to explain how that all fits with ACTIV. Jon Cohen's story has already confused the issue.

FC

From: Freire, Maria (FNIH) [T] b6

Sent: Wednesday, May 13, 2020 3:24 PM

To: Myles, Renate (NIH/OD) [E] b6; Collins, Francis (NIH/OD) [E] b6; Tabak, Lawrence (NIH/OD) [E] b6; Wholley, David (FNIH) [T] b6

Cc: Burklow, John (NIH/OD) [E] b6; Fine, Amanda (NIH/OD) [E] b6; Wojtowicz, Emma (NIH/OD) [E] b6; Kolberg, Rebecca (NIH/OD) [E] b6; Wolinetz, Carrie (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6; Brodd, Lauren (NIH/OD) [E] b6; Schwetz, Tara (NIH/OD) [E] b6; Hallett, Adrienne (NIH/OD) [E] b6; Higgins, Lauren (NIH/OD) [E] b6; Meltzer, Abbey (FNIH) [T] b6; Gorman, Greta (FNIH) [T] b6; Schwetz, Tara (NIH/OD) [E]

APAR0000002906

b6

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Renate,

I have looked at the NIH ACTIV webpage outline and communications and legislative strategy. Thank you for sending them.

The webpage outline is generally fine, Abbey will send you some specific comments. Please note that we have not made the names of the WG participants public in such a visible way. I have no concerns about this, although it appears that the NIH participants are more cautious about having their names out there.

On the communications and legislative strategy, it was very good to see that Carrie's shop is featured prominently. They do an outstanding job at putting together the summaries and technical descriptions of the activities of the PPPs, as they have done in AMP and HEAL.

You have identified some portions for FNIH input. Abbey will reach out directly to you to clarify exactly what you anticipate to be the FNIH role in this.

Thanks, Maria

From: Myles, Renate (NIH/OD) [E] b6

Sent: Tuesday, May 12, 2020 2:43 PM

To: Collins, Francis (NIH/OD) [E] b6; Tabak, Lawrence (NIH/OD) [E] b6;

Freire, Maria (FNIH) [T] b6; Wholley, David (FNIH) [T] b6;

Cc: Burklow, John (NIH/OD) [E] b6; Fine, Amanda (NIH/OD) [E] b6;

Wojtowicz, Emma (NIH/OD) [E] b6; Kolberg, Rebecca (NIH/OD) [E] b6;

Wolinetz, Carrie (NIH/OD) [E] b6; Parker, Ashley (NIH/OD) [E] b6; Brodd,

Lauren (NIH/OD) [E] b6; Schwetz, Tara (NIH/OD) [E] b6; Hallett, Adrienne

(NIH/OD) [E] b6; Higgins, Lauren (NIH/OD) [E] b6; Meltzer, Abbey (FNIH)

[T] b6; Gorman, Greta (FNIH) [T] b6; Schwetz, Tara (NIH/OD) [E]

b6

Subject: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good afternoon:

In the interest of time, I wanted to share the attached two items for both NIH and FNIH leadership review. Attached are:

1) Draft web content for a proposed NIH ACTIV web page:

- Currently, the content is based primarily on publicly available information (mostly pulled from the release).
- The only new content is the listing of the Executive Committee and Working Group members.
- Having an ACTIV webpage will provide interested stakeholders with a central resource for ACTIV information, including releases, scientific papers, blogs, etc.; will point people to the scientific portal for submitting assets; and would allow us to provide status updates, as appropriate and as desired, on ACTIV developments.
- This page can be expanded when we are ready to make more information public.

2) Draft ACTIV Communication and Legislative Strategy:

- The strategy includes proposed tactics that could be developed in the near term, as well as longer lead items that we can prepare for now as we consider appropriate timing.

If it's helpful, we'd be happy to participate in a call to talk through these recommendations with you. We look forward to your feedback.

Best,
Renate

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: b6

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/14/2020 2:39:04 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: JAMA Viewpoint on ACTIV: please review

I think I forwarded it twice. Do you have what you need now?

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:10 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

I need the list of e-mails for the Exec Comm and Working Group members – was that coming from Cheryl? Did I miss it?

FC

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 8:16 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Francis:

Below is suggested language; feel free to modify as you deem appropriate. Renate

Subject: ACTION: Making your ACTIV Participation Public

Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please let me know by 3:00 p.m. ET tomorrow, Thursday, May 14, if you agree to be listed as part of the ACTIV membership.**

From: Myles, Renate (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 6:41 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg,

Rebecca (NIH/OD) [E] <[b6]>
Cc: Burklow, John (NIH/OD) [E] <[b6]>; Tabak, Lawrence (NIH/OD) [E] <[b6]>
Wholley, David (FNIH) [T] <[b6]>; Melencio, Cheryl (FNIH) [T] <[b6]> Parker, Ashley
(NIH/OD) [E] <[b6]>
Subject: RE: JAMA Viewpoint on ACTIV: please review

I'm happy to draft the email message for you. Will send it your way this evening.

From: Collins, Francis (NIH/OD) [E] <[b6]>
Sent: Wednesday, May 13, 2020 6:37 PM
To: Myles, Renate (NIH/OD) [E] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>; Kolberg,
Rebecca (NIH/OD) [E] <[b6]>
Cc: Burklow, John (NIH/OD) [E] <[b6]>; Tabak, Lawrence (NIH/OD) [E] <[b6]>;
Wholley, David (FNIH) [T] <[b6]>; Melencio, Cheryl (FNIH) [T] <[b6]>; Parker, Ashley
(NIH/OD) [E] <[b6]>
Subject: RE: JAMA Viewpoint on ACTIV: please review

I'm glad to send the query if someone will draft the message and someone else (Cheryl?) will send me the list of e-mails for all of the WG members.

From: Myles, Renate (NIH/OD) [E] <[b6]>
Sent: Wednesday, May 13, 2020 6:12 PM
To: Collins, Francis (NIH/OD) [E] <[b6]>; Parker, Ashley (NIH/OD) [E] <[b6]>; Kolberg,
Rebecca (NIH/OD) [E] <[b6]>
Cc: Burklow, John (NIH/OD) [E] <[b6]>; Tabak, Lawrence (NIH/OD) [E] <[b6]>;
Wholley, David (FNIH) [T] <[b6]>
Subject: RE: JAMA Viewpoint on ACTIV: please review

No surprise there. We need to get permission from the EC/WG members quickly. What's the best way to do this?

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: [b6]

From: Collins, Francis (NIH/OD) [E] <[b6]>
Sent: Wednesday, May 13, 2020 5:48 PM
To: Parker, Ashley (NIH/OD) [E] <[b6]>; Kolberg, Rebecca (NIH/OD) [E] <[b6]>
Cc: Myles, Renate (NIH/OD) [E] <[b6]>; Burklow, John (NIH/OD) [E] <[b6]>; Tabak,
Lawrence (NIH/OD) [E] <[b6]>; Wholley, David (FNIH) [T] <[b6]>
Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

Can you give these galley proofs a very close read, and let me know if you find anything amiss?

Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

From: Stacy Christiansen [b6]
Sent: Wednesday, May 13, 2020 5:22 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Howard Bauchner [b6]; Karen Bucher [b6]
Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,

Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

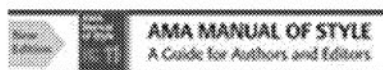
Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA

Managing Editor, *JAMA*

Chair, *AMA Manual of Style*



From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 5/14/2020 4:06:03 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolberggr]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Higgins, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfde4719d7ac48e4a60b2ecd1969a716-higginsl]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Francis, this is not a new restriction. My folks are working on a webpage where the FNIH will include the logos and link to the NIH webpage, as we have done before. M.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:57 AM
To: Burklow, John (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Really? That seems like an odd restriction. But OK, let's do what we have to.

From: Burklow, John (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:39 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]>
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi, Francis—

We have a policy, worked out with OGC, where we don't include company logos on the NIH website. That said, FNIH could certainly post them. We'll come up with a graphic that includes the partners, etc., for the NIH page.

Thanks,

John

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:18 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

How about these two?

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 8:03 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis:

You mentioned that there are images in the presentations that we can use on the webpage, but those images seem very detailed and appear to contain confidential information to me. Would you let me know which particular image that you and David feel represents the overall program but doesn't give away too much information?

We're going to start building the page in draft today (not public).

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]

Sent: Wednesday, May 13, 2020 4:59 PM

To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thanks, all. This is great information. I can add the items from Francis and David to the strategic comms plan and will look for comments from Abbey on the webpage/plan.

Will FNIH reach out to the EC/WG members to ask permission for listing them on the website? We'd love to get this page up this week, if possible.

Best,
Renate

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 4:38 PM

To: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good points.

From: Wholley, David (FNIH) [T] [b6]

Sent: Wednesday, May 13, 2020 4:19 PM

To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis: two other things that are possible and not already on your list below 1) the position paper from the ACTIV Vaccines WG on the issue of doing human challenge trials for Vaccines which I would hope would be ready for release by some time next week 2) a monoclonal antibodies master protocol, timing TBD (since we just received the charge this morning)

David

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 4:07 PM

To: Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi all,

I too want to say thanks to Renate for putting together this draft of the web page – it will be great to have something posted soon.

Building off of presentations to the Leadership Team/Exec Comm, we have a number of visuals that might be appropriate to include, and that would make the web site more pleasing to the eye.

I would be in favor of including the members of the working groups (it's a very impressive list) but only after asking their permission. It would also be good to designate the co-chairs of each of the Working Groups.

The Comms and Leg plan also looks good, though obviously there are uncertainties about the timing of various newsworthy events. In the not too distant future, I think we can imagine these developments:

- 1) Publication of the JAMA Viewpoint – Howard Bauchner has been moving this along at a very rapid pace, I wouldn't be surprised to see the publication emerge within the next week. Would that be a good moment to launch the web site?
- 2) Next week's planned summit, convened by ACTIV, on development of a master protocol(s) for monoclonal Abs – the meeting itself will be closed, but it might be possible to acknowledge that it's happening – as we did for the HEAL initiative a few times.
- 3) The launch of the anticoagulation four-arm trial, with leadership from NHLBI but under the ACTIV umbrella – I don't know exactly what the time table might be

- 4) The launch of the immunomodulator trial – which awaits working out the arrangements with the companies supplying the drugs, and then doing the match with the clinical trial networks that can make this work (through ACTT3)
- 5) The development and announcement of the harmonized master protocol for vaccines, with expectation that the first volunteers will be enrolled in the Ph II/III trials around July 1.

In the midst of all this, it looks like the US government is on the brink of announcing the joint HHS-DOD Manhattan Project 2, aka Operation Warp Speed, with Moncef Slaoui (former GSK) recruited to be the big kahuna, and a general from DoD as deputy. We will need to have materials ready to explain how that all fits with ACTIV. Jon Cohen's story has already confused the issue.

FC

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 3:24 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Renate,

I have looked at the NIH ACTIV webpage outline and communications and legislative strategy. Thank you for sending them.

The webpage outline is generally fine, Abbey will send you some specific comments. Please note that we have not made the names of the WG participants public in such a visible way. I have no concerns about this, although it appears that the NIH participants are more cautious about having their names out there.

On the communications and legislative strategy, it was very good to see that Carrie's shop is featured prominently. They do an outstanding job at putting together the summaries and technical descriptions of the activities of the PPPs, as they have done in AMP and HEAL.

You have identified some portions for FNIH input. Abbey will reach out directly to you to clarify exactly what you anticipate to be the FNIH role in this.

Thanks, Maria

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 2:43 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good afternoon:

In the interest of time, I wanted to share the attached two items for both NIH and FNIH leadership review. Attached are:

- 1) Draft web content for a proposed NIH ACTIV web page:
 - Currently, the content is based primarily on publicly available information (mostly pulled from the release).
 - The only new content is the listing of the Executive Committee and Working Group members.
 - Having an ACTIV webpage will provide interested stakeholders with a central resource for ACTIV information, including releases, scientific papers, blogs, etc.; will point people to the scientific portal for submitting assets; and would allow us to provide status updates, as appropriate and as desired, on ACTIV developments.
 - This page can be expanded when we are ready to make more information public.
- 2) Draft ACTIV Communication and Legislative Strategy:
 - The strategy includes proposed tactics that could be developed in the near term, as well as longer lead items that we can prepare for now as we consider appropriate timing.

If it's helpful, we'd be happy to participate in a call to talk through these recommendations with you. We look forward to your feedback.

Best,
Renate

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: [b6]

From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 5/14/2020 2:28:30 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Tabak, Lawrence (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02e22836b5ff4e9988e3770cfc7ee770-tabakl]
CC: Burklow, John (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e57f267323b43c08be856acb5b964ca-burklowj]; Fine, Amanda (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61290b74aa9a44358954c45439ffdeb6-fineab]; Wojtowicz, Emma (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45c6610aca6e44a08d497630425e5ecd-wojtowiczem]; Kolberg, Rebecca (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=30071513c5a8433a98883fd78d360a91-kolberg]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]; Hallett, Adrienne (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1705e2e7c254b84a77f058dbf75b31b-hallettaa]; Higgins, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfde4719d7ac48e4a60b2ecd1969a716-higginsl]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Gorman, Greta (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=280703da933d491586841696e460f062-gormanmj]; Schwetz, Tara (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b1da1e9650d44fa9a9e2d94f24b5035-schwetzta]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Those are fine with me.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:18 AM
To: Myles, Renate (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

How about these two?

From: Myles, Renate (NIH/OD) [E] [b6]

Sent: Thursday, May 14, 2020 8:03 AM

To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis:

You mentioned that there are images in the presentations that we can use on the webpage, but those images seem very detailed and appear to contain confidential information to me. Would you let me know which particular image that you and David feel represents the overall program but doesn't give away too much information?

We're going to start building the page in draft today (not public).

Thanks,
Renate

From: Myles, Renate (NIH/OD) [E]

Sent: Wednesday, May 13, 2020 4:59 PM

To: Collins, Francis (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]

Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Thanks, all. This is great information. I can add the items from Francis and David to the strategic comms plan and will look for comments from Abbey on the webpage/plan.

Will FNIH reach out to the EC/WG members to ask permission for listing them on the website? We'd love to get this page up this week, if possible.

Best,
Renate

From: Collins, Francis (NIH/OD) [E] [b6]

Sent: Wednesday, May 13, 2020 4:38 PM

To: Wholley, David (FNIH) [T] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate

(NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6];
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good points.

From: Wholley, David (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 4:19 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Myles, Renate
(NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6];
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi Francis: two other things that are possible and not already on your list below 1) the position paper from the ACTIV Vaccines WG on the issue of doing human challenge trials for Vaccines which I would hope would be ready for release by some time next week 2) a monoclonal antibodies master protocol, timing TBD (since we just received the charge this morning)

David

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 4:07 PM
To: Freire, Maria (FNIH) [T] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Tabak, Lawrence
(NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6];
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6];
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]

Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Hi all,

I too want to say thanks to Renate for putting together this draft of the web page – it will be great to have something posted soon.

Building off of presentations to the Leadership Team/Exec Comm, we have a number of visuals that might be appropriate to include, and that would make the web site more pleasing to the eye.

I would be in favor of including the members of the working groups (it's a very impressive list) but only after asking their permission. It would also be good to designate the co-chairs of each of the Working Groups.

The Comms and Leg plan also looks good, though obviously there are uncertainties about the timing of various newsworthy events. In the not too distant future, I think we can imagine these developments:

- 1) Publication of the JAMA Viewpoint – Howard Bauchner has been moving this along at a very rapid pace, I wouldn't be surprised to see the publication emerge within the next week. Would that be a good moment to launch the web site?
- 2) Next week's planned summit, convened by ACTIV, on development of a master protocol(s) for monoclonal Abs – the meeting itself will be closed, but it might be possible to acknowledge that it's happening – as we did for the HEAL initiative a few times.
- 3) The launch of the anticoagulation four-arm trial, with leadership from NHLBI but under the ACTIV umbrella – I don't know exactly what the time table might be
- 4) The launch of the immunomodulator trial – which awaits working out the arrangements with the companies supplying the drugs, and then doing the match with the clinical trial networks that can make this work (through ACTT3)
- 5) The development and announcement of the harmonized master protocol for vaccines, with expectation that the first volunteers will be enrolled in the Ph II/III trials around July 1.

In the midst of all this, it looks like the US government is on the brink of announcing the joint HHS-DOD Manhattan Project 2, aka Operation Warp Speed, with Moncef Slaoui (former GSK) recruited to be the big kahuna, and a general from DoD as deputy. We will need to have materials ready to explain how that all fits with ACTIV. Jon Cohen's story has already confused the issue.

FC

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, May 13, 2020 3:24 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]; Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne (NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]
Subject: RE: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Renate,

I have looked at the NIH ACTIV webpage outline and communications and legislative strategy. Thank you for sending them.

The webpage outline is generally fine, Abbey will send you some specific comments. Please note that we have not made the names of the WG participants public in such a visible way. I have no concerns about this, although it appears that the NIH participants are more cautious about having their names out there.

On the communications and legislative strategy, it was very good to see that Carrie's shop is featured prominently. They do an outstanding job at putting together the summaries and technical descriptions of the activities of the PPPs, as they have done in AMP and HEAL.

You have identified some portions for FNIH input. Abbey will reach out directly to you to clarify exactly what you anticipate to be the FNIH role in this.

Thanks, Maria

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Tuesday, May 12, 2020 2:43 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]
Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Fine, Amanda (NIH/OD) [E] [b6]
Wojtowicz, Emma (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Wolinetz, Carrie (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Brodd,
Lauren (NIH/OD) [E] [b6]; Schwetz, Tara (NIH/OD) [E] [b6]; Hallett, Adrienne
(NIH/OD) [E] [b6]; Higgins, Lauren (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH)
[T] [b6]; Gorman, Greta (FNIH) [T] [b6]; Schwetz, Tara (NIH/OD) [E]
[b6]
Subject: FOR YOUR REVIEW: Draft ACTIV Web Page Content and Communication Strategic Plan

Good afternoon:

In the interest of time, I wanted to share the attached two items for both NIH and FNIH leadership review. Attached are:

- 1) Draft web content for a proposed NIH ACTIV web page:
 - Currently, the content is based primarily on publicly available information (mostly pulled from the release).
 - The only new content is the listing of the Executive Committee and Working Group members.
 - Having an ACTIV webpage will provide interested stakeholders with a central resource for ACTIV information, including releases, scientific papers, blogs, etc.; will point people to the scientific portal for submitting assets; and would allow us to provide status updates, as appropriate and as desired, on ACTIV developments.
 - This page can be expanded when we are ready to make more information public.
- 2) Draft ACTIV Communication and Legislative Strategy:
 - The strategy includes proposed tactics that could be developed in the near term, as well as longer lead items that we can prepare for now as we consider appropriate timing.

If it's helpful, we'd be happy to participate in a call to talk through these recommendations with you. We look forward to your feedback.

Best,
Renate

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: [b6]

From: Weinmann, Gail (NIH/NHLBI) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F38A543B4021483BA67E42AF1165DCAD-WEINMANG]
Sent: 5/14/2020 9:05:39 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: Myles, Renate (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d317f5626934585b3692a1823c1b522-mylesr]; Meltzer, Abbey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c341d86cf7404a78ac8f852e698e5382-meltzerak]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]
Subject: RE: Time sensitive: Making your ACTIV Participation Public

Yes, I agree to be listed on the web site as part of the ACTIV team.

Thank you.

Gail G. Weinmann, MD
Deputy Director
Division of Lung Diseases
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, MSC 7952
Bethesda, Maryland 20892 (20817 for Express Mail/FedEx)
Tel: [b6]
Fax: 301-480-3547
[b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 1:17 PM
To: Weinmann, Gail (NIH/NHLBI) [E] [b6]; Mensah, George (NIH/NHLBI) [E] [b6]
Cc: Parker, Ashley (NIH/OD) [E] [b6]; Melencio, Cheryl (FNIH) [T] [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

Hi Gail and George

I got a bounce back because somehow your e-mail addresses weren't quite correct in the original list, so I'm sending you this again.

Thanks, Francis

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 11:00 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Meltzer, Abbey (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: Time sensitive: Making your ACTIV Participation Public

Dear ACTIV Colleagues:

Yes, this message is for you, though your address was in the bcc line!

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please send your responses to me, cc'ing Renate Myles, Abbey Meltzer, and David Wholley by 12:00 p.m. ET tomorrow, Friday, May 15, if you agree to be listed on the web site as part of the ACTIV team.**

Thanks,
Francis

Francis S. Collins, MD, PhD
NIH Director

From: Myles, Renate (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7D317F5626934585B3692A1823C1B522-MYLESR]
Sent: 5/14/2020 2:12:43 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Yes, please!

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, May 14, 2020 10:04 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Also, what is the update time and date to have this back? Tomorrow 12PM?

From: Parker, Ashley (NIH/OD) [E]
Sent: Thursday, May 14, 2020 10:03 AM
To: Myles, Renate (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Shouldn't Francis cc you, Abbey, and David? Please let me know, I am packaging this to make it easy for him to send.

Thanks!
Ashley

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 8:16 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

Hi Francis:

Below is suggested language; feel free to modify as you deem appropriate. Renate

Subject: ACTION: Making your ACTIV Participation Public

Dear Colleagues:

NIH would like to launch an ACTIV webpage to provide stakeholders with a central resource for information about our efforts, including announcements, scientific papers, and new developments. Currently, the content is based on publicly available information, but we would like add the ACTIV leadership and working group members. Your representation on

ACTIV demonstrates the breadth and depth of expertise and experience from all sectors committed to this effort. **Please let me know by 3:00 p.m. ET tomorrow, Thursday, May 14, if you agree to be listed as part of the ACTIV membership.**

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 6:41 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

I'm happy to draft the email message for you. Will send it your way this evening.

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 6:37 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]; Melencio, Cheryl (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

I'm glad to send the query if someone will draft the message and someone else (Cheryl?) will send me the list of e-mails for all of the WG members.

From: Myles, Renate (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 6:12 PM
To: Collins, Francis (NIH/OD) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: JAMA Viewpoint on ACTIV: please review

No surprise there. We need to get permission from the EC/WG members quickly. What's the best way to do this?

Renate Myles, MBA
Deputy Director for Public Affairs
Office of Communications and Public Liaison
National Institutes of Health
Tel: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, May 13, 2020 5:48 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Kolberg, Rebecca (NIH/OD) [E] [b6]
Cc: Myles, Renate (NIH/OD) [E] [b6]; Burklow, John (NIH/OD) [E] [b6]; Tabak, Lawrence (NIH/OD) [E] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: FW: JAMA Viewpoint on ACTIV: please review

Hey Ashley and Rebecca,

Can you give these galley proofs a very close read, and let me know if you find anything amiss?

Renate, note that they are asking for the ACTIV website URL. Very timely, I'd say!

Francis

From: Stacy Christiansen [REDACTED] b6
Sent: Wednesday, May 13, 2020 5:22 PM
To: Collins, Francis (NIH/OD) [E] [REDACTED] b6
Cc: Howard Bauchner [REDACTED] b6; Karen Bucher [REDACTED] b6
Subject: JAMA Viewpoint on ACTIV: please review

Dear Dr Collins,

Attached please find a proof of your Viewpoint for JAMA on the ACTIV initiative. We have typeset your figure herein, and I am cc'ing the illustrator, Karen Bucher, so we can handle any text or graphics changes simultaneously.

The only query to you is the completion of reference 5, the ACTIV portal URL.

I recognize how busy you must be, but I hope you can find time to review this proof so we can publish it quickly.

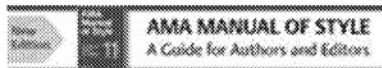
Thank you so much!

Best, Stacy

Stacy L. Christiansen, MA

Managing Editor, *JAMA*

Chair, *AMA Manual of Style*



From: Brodd, Lauren (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BA665DEA08E54171B3D6890C2518DDB9-LEPONELM]
Sent: 2/1/2021 9:16:50 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: preclinical WG roster- thread about Frank Stegmeier

Hi Ashley,

Below is the thread about Frank. Based on the info below, I think he should be removed. Do you want me to double check with Cheryl, or go with this info? Sent you a text but I also think there's an issue with her roster, which is easier to discuss via phone.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 2:26 PM
To: Wojtowicz, Emma (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Hi Emma,

There is no replacement for Frank at the moment. David Meeker is the rep for Rhythm however he is on the leadership team (we do not list them) and he does not participate in the WGs.

For background, David use to be a top official/CEO at KSQ and has now moved to Rhythm. Frank was the appointed WG rep by David for KSQ but apparently no longer participates and had minimal interaction during his appointed time.

Thanks again,
Ashley

From: Wojtowicz, Emma (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 2:04 PM
To: Parker, Ashley (NIH/OD) [E] [b6]; Myles, Renate (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Thanks, Ashley. We will update the landing page. Is Frank Stegmeier being replaced on the WG with someone from Rhythm Therapeutics?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, September 30, 2020 12:51 PM
To: Myles, Renate (NIH/OD) [E] [b6]; Wojtowicz, Emma (NIH/OD) [E] [b6]; Brodd, Lauren (NIH/OD) [E] [b6]
Subject: FW: ACTIV Briefing slides updated 9-30-20.pptx

Hi all,

Per David's note below: KSQ Therapeutics is no longer an ACTIV industry partner and should be replaced with Rhythm Therapeutics on our list of industry partners on the website. David must have already notified the FNIH COMMs team as the change was updated at some point today on their site <https://fnihi.org/what-we-do/programs/activ-partnership>.

Apparently, Frank Stegmeier listed on the preclinical WG roster for KSQ Tx is no longer a participant – not sure if we should remove his name from the public preclinical list or keep it since he was on the group at some point? Renate and Emma, I defer to your preference.

Lauren – can you please remove Frank S. from our preclinical roster on the excel sheet?

Including FNIH's updated ACTIV slides as FYI only.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Wednesday, September 30, 2020 12:16 PM
To: Parker, Ashley (NIH/OD) [E] <[b6]>; Collins, Francis (NIH/OD) [E] <[b6]>; Tabak, Lawrence (NIH/OD) [E] <[b6]>; Lane, Cliff (NIH/NIAID) [E] <[b6]>; Freire, Maria (FNIH) [T] <[b6]>; Austin, Christopher (NIH/NCATS) [E] <[b6]>; Anderson, James (NIH/OD) [E] <[b6]>
Cc: Gonzalez, Nina <ningonzalez@deloitte.com>; Appell, Evan <eappell@deloitte.com>; Adam, Stacey (FNIH) [T] <[b6]>; Menetski, Joseph (FNIH) [T] <[b6]>
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Please see my answers to your questions below, in italics. Revised set attached. Thanks for your close read, Ashley!

From: Parker, Ashley (NIH/OD) [E] <[b6]>
Sent: Wednesday, September 30, 2020 9:50 AM
To: Collins, Francis (NIH/OD) [E] <[b6]>; Wholley, David (FNIH) [T] <[b6]>; Tabak, Lawrence (NIH/OD) [E] <[b6]>; Lane, Cliff (NIH/NIAID) [E] <[b6]>; Freire, Maria (FNIH) [T] <[b6]>; Austin, Christopher (NIH/NCATS) [E] <[b6]>; Anderson, James (NIH/OD) [E] <[b6]>
Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Hi David,

Looks great! Please see comments attached and below.

- Slide 3 – replaced KSQ Tx with Rhythm (do we need to do the same on the ACTIV and FNIH websites?). The preclinical WG has a rep from KSQ Tx although David Meeker has moved to Rhythm (20 or 21 industry partners?) -- *not sure how this happened, but Deloitte and I had discussed making this same change and when I double-checked the version I sent Francis and the group last night, it showed only Rhythm, not KSQ. The KSQ rep on the Preclinical WG is no longer there and did not contribute much, so we should remove KSQ from the lists and indeed update both the NIH and FNIH websites.*
- Slide 3 – add FNIH to non-profit section or move logo on the far left to the non-profit section? *I believe your comment says FNIH is listed on the NIH website in this way, so yes, I've listed NIH and boosted the number of non-profits to 4.*
- Slide 7 – missing ACTIV data and inventory efforts (arrow) – *that's deliberate. That effort pretty much wound up in June and has been subsumed into the NCATS and other databases. No need to include it.*
- Slide 12 – is ACTIV-5 still projected to launch this week? *I checked with John Beigel, and they are still waiting to get their final safe to proceed from FDA. They are expecting this Friday, but next week (Oct. 5) is the new "projected" date. I have made the change.*
- Slide 13 – agree with Francis - *yes, this slide is gone*
- Slides 14-16 – mention the CTC WG has completed all activities on one of these slides or just say verbally? – *just say verbally. The three checkmarks tell the tale.*

- Slide 18 – Current language on the slide is fine but the NIH portal language is in the process of being revised. Interested parties should submit diagnostics, vaccines, technologies, or other information for awareness of NIH. All preclinical and clinical therapeutics will be routed to the ACTIV portal. – *I corrected the language by replacing what was on the slide with your second sentence here.*

Thanks and good luck tomorrow.

Ashley

From: Collins, Francis (NIH/OD) [E] <[b6]>

Sent: Tuesday, September 29, 2020 11:21 PM

To: Wholley, David (FNIH) [T] <[b6]> Tabak, Lawrence (NIH/OD) [E] <[b6]> Lane, Cliff (NIH/NIAID) [E] <[b6]> Freire, Maria (FNIH) [T] <[b6]>; Austin, Christopher (NIH/NCATS) [E] <[b6]> Parker, Ashley (NIH/OD) [E] <[b6]>; Anderson, James (NIH/OD) [E] <[b6]>

Subject: RE: ACTIV Briefing slides updated 9-30-20.pptx

Looks like a definite upgrade! Lots of good stuff here. But I have concerns about Klick and slide 13, that needs to go.

FC

From: Wholley, David (FNIH) [T] <[b6]>

Sent: Tuesday, September 29, 2020 9:00 PM

To: Collins, Francis (NIH/OD) [E] <[b6]> Tabak, Lawrence (NIH/OD) [E] <[b6]>; Lane, Cliff (NIH/NIAID) [E] <[b6]>; Freire, Maria (FNIH) [T] <[b6]>; Austin, Christopher (NIH/NCATS) [E] <[b6]> Parker, Ashley (NIH/OD) [E] <[b6]>; Anderson, James (NIH/OD) [E] <[b6]>

Subject: ACTIV Briefing slides updated 9-30-20.pptx

A refreshed, redesigned high level ACTIV PowerPoint deck for you all. You can share any thoughts by email, or in war room tomorrow, if you'd like.

From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/11/2020 6:44:51 PM
To: Higgins, Joni C. [b6]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Mauck, Danielle [b6]; Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Joni,

Nice to e-meet you as well. Please let me introduce Cheryl Melencio, Administrative Manager in Research Partnerships, who will work with Danielle to find a good time for a call.

Looking forward to talking with you.
Karen

From: Higgins, Joni C. [b6]
Sent: Monday, May 11, 2020 2:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Mauck, Danielle [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Ashley, thanks so much for making the connection.

Karen, David, it is nice to e-meet you. I am copying my colleague Danielle Mauck, who serves as BayCare's Director of Sponsored Programs and Research, to compare calendars.

We look forward to connecting with you to discuss your work and how we might help.

Joni

Joni Higgins
Federal Government Relations Manager

BayCare Health System

b6

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 2:04 PM
To: Higgins, Joni C. [b6]
Cc: Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

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Hi Joni,

I am cc'ing Karen Tauntas and David Wholley with FNIH who are coordinating the efforts with ACTIV to find a time that best fits for you to speak with them.

Best,
Ashley

From: Higgins, Joni C. [b6]
Sent: Monday, May 11, 2020 1:32 PM
To: Parker, Ashley (NIH/OD) [E]; [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Ashley, thanks so much for your note. I appreciate the quick follow-up. Do you think a call at some point this week might be a possibility?

Joni

From: Parker, Ashley (NIH/OD) [E]; [b6]
Sent: Monday, May 11, 2020 1:24 PM
To: Higgins, Joni C. [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

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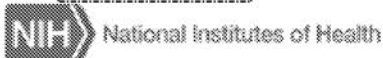
Hi Joni,

Thank you for sharing BayCare Health System's interest in becoming involved as a large non-profit hospital system with ACTIV. We are in the process of developing a portal to receive submissions from interested partners however in the meantime I am triaging these request for our working groups.

I've entered the information you've provided below into our database and will share this information with leads of our ACTIV clinical capacity working group to follow up with you.

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]



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From: Wooldridge, Shannon (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=385B0C281F104789873E956DC91B7C06-BURDENSE]
Sent: 5/11/2020 6:28:08 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

I'll add this.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 2:23 PM
To: Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: FW: Question re: ACTIV and BayCare Health System (Florida)

Sorry – updated email thread on this topic.

From: Higgins, Joni C [b6]
Sent: Monday, May 11, 2020 2:12 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Mauck, Danielle [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

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Joni

Joni Higgins
Federal Government Relations Manager

BayCare Health System

[b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 2:04 PM
To: Higgins, Joni C. [b6]
Cc: Tountas, Karen (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

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malicious emails and contact the IS Service Desk with all other suspicious activity.

Hi Joni,

I am cc'ing Karen Tauntas and David Wholley with FNIH who are coordinating the efforts with ACTIV to find a time that best fits for you to speak with them.

Best,
Ashley

From: Higgins, Joni C. [b6]
Sent: Monday, May 11, 2020 1:32 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

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Joni

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 1:24 PM
To: Higgins, Joni C. [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

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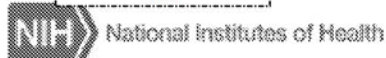
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Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]



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From: Tountas, Karen (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=40C04FEF6F1E46F5B750753CD5A14F93-TOUNTASKH]
Sent: 5/11/2020 5:53:23 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Hi Ashley,

Thank you for forwarding this inquiry. Cataloging such settings will be very important for ACTIV overall. The Inventory and Survey subgroups are both meeting this week. I propose that I get in touch with them via email to explain the inventory goals of the CTC WG, and let them know that we are administering surveys to gain an understanding of capabilities and capacities and ask them if they are interested in participating.

How does that sound?
Karen

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 1:42 PM
To: Wholley, David (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Would a call with BayCare Health be of interest? Leaving it to both of you to decide and follow up if interested.

Thanks,
Ashley

From: Higgins, Joni C. [b6]
Sent: Monday, May 11, 2020 1:32 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

Ashley, thanks so much for your note. I appreciate the quick follow-up. Do you think a call at some point this week might be a possibility?

Joni

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 11, 2020 1:24 PM
To: Higgins, Joni C. [b6]
Subject: RE: Question re: ACTIV and BayCare Health System (Florida)

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Hi Joni,

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I've entered the information you've provided below into our database and will share this information with leads of our ACTIV clinical capacity working group to follow up with you.

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health

Tel: [REDACTED] b6



National Institutes of Health

From: Higgins, Joni C. [REDACTED] b6
Sent: Monday, May 11, 2020 12:19 PM
To: Parker, Ashley (NIH/OD) [E] [REDACTED] b6
Subject: Question re: ACTIV and BayCare Health System (Florida)

Hi, Ashley,

I am writing at the suggestion of House Energy & Commerce Committee staff, who suggested you would be a great person with whom to start with a brief question outlined below.

I lead federal advocacy for BayCare Health System, one of Florida's largest not-for-profit health systems, comprised of 15 hospitals and approximately 30,000 team members and physicians in West Central Florida (Tampa Bay area).

BayCare was glad to see last month's announcement regarding the creation of the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership. As ACTIV continues its work, **is there someone on the team with whom we could speak about becoming involved as a large, not-for-profit hospital system in the State of Florida?**

We view this as a significant and very much needed development to help coordinate many different aspects of COVID-related research, and we would appreciate any insight you would have to connect with the group and its efforts.

Thanks so much,
Joni

Joni Higgins
Federal Government Relations Manager

BayCare Health System

[REDACTED] b6

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From: Higgs, Elizabeth (NIH/NIAID) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0601CA55A82841ABA16353B96CFF8CA9-EHIGGS]
Sent: 5/7/2020 6:08:20 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Erlandson, Karl (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6065f551f0224ed280110d770df55185-karl.erland]
CC: Armstrong, Kimberly (OS/ASPR/BARDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1ba1621e98a14536995671b6a71caf1e-Kimberly.Ar]
Subject: Re: POC for candidate therapeutics for ACTIV

Hi Karl,

From an accelerating clinical development perspective we are leveraging all the clinical trials capacities across the 27 institutes and centers which constitute the NIH. NIAID will be bringing ACTT, INSIGHT trials under this umbrella for example.

Libby

From: "Parker, Ashley (NIH/OD) [E]" [b6] />

Date: Thursday, May 7, 2020 at 1:38 PM

To: "Erlandson, Karl (OS/ASPR/BARDA)" [b6]

Cc: "Armstrong, Kimberly (OS/ASPR/BARDA)" [b6]

Subject: RE: POC for candidate therapeutics for ACTIV

Hi Karl,

ACTIV is a public private partnership coordinating by FNIH, with multiple partners from government agencies (NIH, FDA, BARDA, CDC, DOD, EMA) , 18 industry partners, and academia to accelerate therapeutics and vaccines – here is the [link](#) to the NIH press release.

The public private partnership has 4 workings groups with representatives from participating partners: preclinical therapeutics, clinical therapeutics, clinical trial capacity, and vaccines.

If companies are interested in submitting ideas (i.e. preclinical, therapeutics or vaccine candidates to be considered for testing in the clinical trial networks ACTIV is coordinating and leveraging) they are welcome to send these. Please note, these will be shared with the ACTIV working groups which is not limited to government.

David Wholley at FNIH is the main POC for interested companies, however they are welcome to submit inquires directly to me until the portal for ACTIV is launched.

Please let us know if you have additional questions.

Best,
Ashley

From: Erlandson, Karl (OS/ASPR/BARDA) [b6]

Sent: Thursday, May 7, 2020 12:14 PM

To: Parker, Ashley (NIH/OD) [E] [b6] Higgs, Elizabeth (NIH/NIAID) [E] [b6]

Cc: Armstrong, Kimberly (OS/ASPR/BARDA) [b6]

Subject: RE: POC for candidate therapeutics for ACTIV

Thank you Ashley

APAR0000003282

I have many questions as I'm not completely informed on what ACTIV is and who makes up ACTIV. The portal will be very useful when it comes up and will likely answer many of my questions.

What level of information do you need and how do we handle proprietary information? At this point, I think it may be best for the company to provide information directly to you.

b6

FOUO, Procurement Sensitive

From: Parker, Ashley (NIH/OD) [E] **b6** >

Sent: Wednesday, May 6, 2020 2:51 PM

To: Higgs, Elizabeth (NIH/NIAID) [E] **b6** >; Erlandson, Karl (OS/ASPR/BARDA)

b6
Cc: Adam, Stacey (FNIH) [T] **b6**; Walker, Robert (OS/ASPR/BARDA) <**b6**>
Chapman, Joseph (OS/ASPR/BARDA) **b6**; Rigg, John (OS/ASPR) <**b6**>
Merkeley, Tyler (OS/ASPR/BARDA) **b6**; Rashid, Kamilah (NIH/OD) [E] **b6**;
Walsh, Elizabeth (NIH/NIAID) [E] **b6**; Columbus, Megan (NIH/OD) [E] **b6**;
Rosen, David (NIH/OD) [E] **b6**

Subject: RE: POC for candidate therapeutics for ACTIV

Hi Libby and Karl,

Libby – thank you for the introduction.

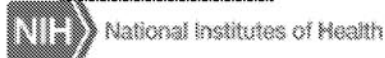
The NIH OD team cc'd here is working to have a portal available for these types of submissions – hopefully before early next week. We are also working closely with a team at BARDA, cc'd to develop a plan to exchange information on therapeutics (preclinical and clinical), diagnostics, and vaccines.

In the meantime, please feel free to send me any information you would like to be included for consideration for ACTIV.

Thank you,
Ashley

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health

Tel: **b6**



From: Higgs, Elizabeth (NIH/NIAID) [E] **b6** >

Sent: Wednesday, May 6, 2020 12:32 PM

To: Erlandson, Karl (OS/ASPR/BARDA) <**b6**>; Parker, Ashley (NIH/OD) [E] **b6**

Cc: Adam, Stacey (FNIH) [T] **b6**; Walker, Robert (OS/ASPR/BARDA) **b6**

Subject: POC for candidate therapeutics for ACTIV

Hi Karl,

Following up on your questions yesterday around the issue of how to funnel products for consideration into ACTIV for consideration in the platform trials. Dr. Ashley Parker is the POC, please send information to her.

Ashley Parker, (NIH/OD) [b6].

Hi Ashley,

Dr. Karl Erlandson is a colleagues from BARDA. They are supporting some of the preclinical work on a polyclonal product (among others), and have been fielding requests for clinical trials.

Also copied is Dr. Bob Walker who is helping chair the interagency working group on clinical trials.

Thanks to all,

Libby

Elizabeth S. Higgs, MD, DTMH, MIA

Global Health Science Advisor

Division of Clinical Research

National Institute of Allergy and Infectious Diseases

NIH, HHS, USG

[b6]

Skype: libbyhiggs2

Cell: [b6]

From: Shah, Monica [b6]
Sent: 5/7/2020 4:46:51 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]
Subject: RE: ACTIV Initiative
Attachments: Novel Trial Design and Covid-19 - Core Capability Deck.pdf; CAGT COE COVID-19 Slides.pdf

Dear David,

Thank you very much for your quick response. Karen, very nice to meet you by e-mail. I'm attaching some information about our novel trial designs for COVID-19 and resources to conduct trials in the pandemic setting.

Karen – if you have some time it would be great to further connect with you to discuss our innovations and commitment to public-private collaboration to accelerate finding a cure.

Thank you.

Sincerely,
Monica

From: Wholley, David (FNIH) [T] [b6]
Sent: Thursday, May 7, 2020 12:01 PM
To: Shah, Monica [b6]
Cc: Freire, Maria (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Tountas, Karen (FNIH) [T] [b6]
Subject: ACTIV Initiative

Hi Monica:

Maria forwarded me your email below. I know you had also previously contacted NIH back on April 23; your email was noted and shared with our NIH colleagues and our working groups as we were still formulating some of our thinking with regard to how we interact with CROs. Our Clinical Trial Capacity Working Group, which is supported by Karen Tountas here at FNIH, is in fact in the process reaching out to a number of the larger CROs with respect to site capacity for COVID-19 trials as well as trial infrastructure and innovation. I have copied Karen on this email; please feel free to reach out to her to learn more.

Regards,
David

From: "Shah, Monica" [b6]
Date: May 7, 2020 at 8:13:11 AM GMT-5
To: "Freire, Maria (FNIH) [T]" [b6]
Subject: ACTIV Initiative

Dear Dr. Freire,

I hope that you are well. My name is Monica Shah and I am the Head of the Cell and Gene Therapy Center of Excellence, which is part of the Division of Design and Delivery Innovation at IQVIA. Prior to joining IQVIA I was at the NIH for almost a decade and held leadership positions at NHLBI and NCATS. My passion is optimizing the clinical research enterprise and accelerating the development of cures through innovation and public-private collaboration.

To that end, IQVIA would be very interested in joining the ACTIV Consortium to accelerate the development of new treatments and vaccines for COVID-19. As you may know, IQVIA (formerly QuintilesIMS) is the world's largest contract research organization (CRO), and has access to unparalleled data assets and analytics and vast array of patient-centered and data-driven resources to optimize the execution of clinical trials.

I was reviewing the impressive list of industry collaborators that are currently participating in the consortium, but saw that there were no CROs included. We think we could bring a complementary perspective and unique set of skills and resources to help the ACTIV Consortium achieve its goals. If possible, we would be delighted to further explore this with you with an introductory conversation.

Thank you and best wishes for success in this endeavor.

Sincerely,
Monica

Monica R. Shah, MD, FACC
Vice President and Head, Cell and Gene Therapy Center of Excellence
Therapeutic Strategy and Science
Design and Delivery Innovations



[Learn more](#) about IQVIA

Washington, DC
USA

O: [REDACTED] b6

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From: Meltzer, Abbey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C341D86CF7404A78AC8F852E698E5382-MELTZERAK]
Sent: 5/6/2020 10:53:48 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: Message from Unknown sender (+13014788379)

Thank you!

Best,
Abbey

Sent from my iPhone

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, May 6, 2020 6:45:55 PM
To: Meltzer, Abbey (FNIH) [T] [b6]
Subject: RE: Message from Unknown sender [b6]

Hi Abbey,

Thank you for sharing -- I am just getting around to listen to the voicemail. We included the Acorn AI information in our spreadsheet and Maria has also shared this with the FNIH leads, please see attached.

Thanks again,
Ashley

-----Original Message-----

From: Meltzer, Abbey (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 12:36 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Message from Unknown sender [b6]

Hi Ashley,

Please see attached for a voicemail we received from someone following up regarding ACTIV.

Best,
Abbey

-----Original Message-----

From: Sepulveda, Dorina (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 9:40 AM
To: Meltzer, Abbey (FNIH) [T] [b6]
Subject: FW: Message from Unknown sender [b6]

Abbey, attached voicemail re covid-19

Dorina Sepúlveda
Executive Assistant to the President
Foundation for the National Institutes of Health
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852
[b6] fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852

Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic

-----Original Message-----

From: Cisco Unity Connection Messaging System [b6]

Sent: Tuesday, May 5, 2020 9:32 AM

To: [b6]

Subject: Message from Unknown sender [b6]

"Yes this is Donna Lock with Meda data and acorn ARI trying to reach Dr. ferrera(?) regarding the information I sent over on a coded 19 synthetic control arm since like 50% of the covert(?) trial are being run on the platform and we could provide a control arm for all the studies that are going on in the industry. I'll try to reach Dr. Freer again but if you'd like please give me a call. My telephone number is."

From: Adam, Stacey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCD875F0679648859E1CF101C0943414-ADAMSJ4]
Sent: 5/6/2020 5:47:17 PM
To: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
Subject: RE: Potential participation in ACTIV

Thanks, Maria.

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Freire, Maria (FNIH) [T] [b6]
Sent: Wednesday, May 6, 2020 1:38 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]
Subject: Fwd: Potential participation in ACTIV

Ashley, for Exec Sec.

Stacey, Mike - FYI and use as appropriate.

Best to all, M.

Begin forwarded message:

From: "Pykett, Mark" [b6]
Date: May 6, 2020 at 12:33:51 PM GMT-5
To: "Freire, Maria (FNIH) [T]" [b6]
Subject: Potential participation in ACTIV

Dear Dr. Freire,

I hope my note finds you all safe and well. My name is Mark Pykett and I am the Chief Scientific Officer of PTC Therapeutics, a biopharmaceutical company located in South Plainfield, NJ. The company is engaged in discovery, development and commercialization of novel therapeutics for rare and neglected diseases with high unmet medical need. PTC has a global footprint of over 900 people and currently has four marketed products.

We have learned with great interest about the planned ACTIV public-private partnership to coordinate and accelerate the development of COVID-19 vaccines and treatment options. PTC has an orally-bioavailable clinical stage compound, PTC299, with a unique, dual-mechanism of action that is highly differentiated from other drugs and we believe has high potential in treating COVID-19 patients. PTC299 is well positioned for human clinical testing as a COVID-19 treatment based on the following reasons:

b4

We would be grateful if you could share with us entry criteria, eligibility requirements for the program, and your view of the next steps for ACTIV. If you need any additional information, I would be happy to provide it.

With kind regards,

Mark

Mark Pykett, VMD, PhD
Chief Scientific Officer

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From: Mascola, John (NIH/VRC) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F78B40A596B4CA4A2850A429D1AE3F2-JMASCOLA]
Sent: 5/5/2020 11:49:32 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Marovich, Mary (NIH/NIAID) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bfd0192d165d4643accf6347728dbaeb-marovichma]; Cohen, Myron [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2141b9e28c1a421fb3c1c4f75dd4c457-myron_cohen]
CC: Tolman, Brett [btolman@deloitte.com]
Subject: RE: ACTIV and antibodies

Thanks.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, May 5, 2020 10:32 AM
To: Santos, Michael (FNIH) [T] [b6]; Mascola, John (NIH/VRC) [E] [b6]; Marovich, Mary (NIH/NIAID) [E] [b6]; Cohen, Myron [b6]
Cc: Tolman, Brett <btolman@deloitte.com>
Subject: RE: ACTIV and antibodies

Hi all,

I will add this to the clinical Tx list – thank you.

Ashley

From: Santos, Michael (FNIH) [T] [b6]
Sent: Tuesday, May 5, 2020 9:43 AM
To: Mascola, John (NIH/VRC) [E] [b6]; Parker, Ashley (NIH/OD) [E] [b6]; Marovich, Mary (NIH/NIAID) [E] [b6]; Cohen, Myron [b6]
Cc: Tolman, Brett <btolman@deloitte.com>
Subject: RE: ACTIV and antibodies

Hi John,

Thanks for raising this – indeed there's a lot of great inquiries about participation coming in.

At a general level, Ashley Parker is coordinating intake of questions like this from companies that are interested in engaging in ACTIV.

At a specific level, based on the conversation yesterday I believe that Mary and Mike are tracking the mAb space closely (at least the antiviral mAb space – if this is a host-directed mAb it may go better to the therapeutics group, but either way Ashley can route it for consideration).

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Mascola, John (NIH/VRC) [E] [b6]
Sent: Monday, May 4, 2020 9:39 PM
To: Santos, Michael (FNIH) [T] [b6]
Subject: ACTIV and antibodies

Mike,

Each time a talk to a company with COVID-19 product – they ask about ACTIV – so that is good!

A small company has a mAb product moving to phase 1 end of summer, to be used first at therapeutic.

Company is Bria Biosciences and head is Zhi Hong. [b6]

Is there a subgroup within ACTIV that has some focus on antibody therapeutics. And if so, can this company be invited?

Thanks
John

From: Wooldridge, Shannon (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=385B0C281F104789873E956DC91B7C06-BURDENSE]
Sent: 5/4/2020 7:40:56 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: RE: Covid-19 Vaccine Project Concept

Never mind – I missed the original email. Sorry!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 3:40 PM
To: Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: RE: Covid-19 Vaccine Project Concept

Cheryl did not include an attachment but I can ask.

From: Wooldridge, Shannon (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 3:38 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Covid-19 Vaccine Project Concept

Did you mean to include an attachment?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, May 4, 2020 3:31 PM
To: Wooldridge, Shannon (NIH/OD) [E] [b6]
Subject: FW: Covid-19 Vaccine Project Concept

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 2:02 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: FW: Covid-19 Vaccine Project Concept

Hi Ashley

This gentleman has been calling me the last couple days trying to send his concept for the ACTIV project. He asked that when you receive it you could confirm receipt. It wasn't coming through to my FNIH email so I had him send it to my personal email. I'm not sure why it doesn't go through.

Thank you

Cheryl

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]

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fnih.org

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Donate to the FNIH's Pandemic Response Fund to combat COVID-19: fnih.org/pandemic



----- Forwarded Message -----

From: Howard Jeffrey Bender

b6

To:

b6

Sent: Monday, May 4, 2020, 01:22:55 PM EDT

Subject: Covid-19 Vaccine Project Concept

Hello, Cheryl -

Thanks for your help this morning. Here's my project concept.

Using available NIH databases, my independent research has found three one-in-a-million nucleotide links between the coronavirus and the human genome, forming the D-loop of tRNA. For the past year my work has been followed by your colleague, Kristofor Langlais [b6], who suggested I continue with lab research needed to confirm my results and speculations. My work is generally described in a YouTube for folks interested in this topic, titled Coronavirus - Using Your DNA Against You. It includes fundamental descriptions but is only about 11 minutes long.

It seems that most vaccine research is focused on finding the right immune cell proteins to keep the coronavirus from infecting human cells in the first place. I'm approaching it differently, with the speculation that at least one of those related nucleotide sequences is part of the reason Covid-19 can become so virulent. As described in the YouTube, if zapping those sequences causes Covid-19 to be a relatively mild infection, perhaps our immune system will form antibodies against it and, by extension, the deadly virus. BTW, I've found different tRNA sequences in both SARS and MERS.

I'm not looking for personal funding, but am asking for a lab researcher to test my concepts and whatever funds are necessary to do it. I suggest four levels, mentioned in the YouTube, with the project stopped for a failure at any level. Those levels are:

1. Using CRISPR or another nucleotide editing system, zap those three sequences in the virus. Whole genome nucleotide sequencing must be done to ensure those sequences have been removed.
2. Using cloned animals, infect one group with the original coronavirus and the other group with the zapped coronavirus. If the zapped animals remain much healthier than the control group, this test will be considered successful.
3. After the healthier animals have fully recovered, infect them with the original coronavirus. If they remain relatively healthy, their immune systems have developed the necessary antibodies, possibly a vaccine from the coronavirus, and this test will be considered successful.
4. Now testing can be done with human subjects, with the hope that humans will also form the necessary antibodies as a self-vaccine, with the researcher watching for any dangerous side effects and other diseases the coronavirus can still create.

If you think my ideas may have merit and can point me to an experimenter to do those tests, we may all defeat this deadly virus.

APAR0000003310

Thanks for any help you can offer.

Cheers,

Howard

Howard Jeffrey Bender, Ph.D.

From: Freire, Maria (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8598D551D1D3455EAF14854C83F41D84-FREIREMC]
Sent: 5/5/2020 2:27:52 AM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]; Tountas, Karen (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40c04fef6f1e46f5b750753cd5a14f93-tountaskh]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: Control Arm for COVID-19 Trials

Thanks Stacey. Noted.

On May 4, 2020, at 9:18 PM, Adam, Stacey (FNIH) [T] [b6] wrote:

Hi Maria,

I think you can reply that you have sent to NIH.

However, Karen, it is worth noting for both of us, as many of the NIH clinical trial networks operate on a Medidata system such as RAVE that feeds can feed into this platform. So while not immediately applicable, could be something to consider if we have to start pulling data across networks with a compatible platform.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Freire, Maria (FNIH) [T] [b6]
Sent: Monday, May 4, 2020 11:28 AM
To: Wholley, David (FNIH) [T] [b6]; Adam, Stacey (FNIH) [T] [b6]; Santos, Michael (FNIH) [T] [b6]; Tountas, Karen (FNIH) [T] [b6]; Parker, Ashley (NIH/OD) [E]
Subject: FW: Control Arm for COVID-19 Trials

Ashley,

For your inclusion in your database.

WG – let me know if this is of any use for you. Otherwise I will reply that I have sent this to the NIH. M.

From: Donna Locke [b6]
Sent: Friday, May 1, 2020 10:22 AM
To: Freire, Maria (FNIH) [T] [b6]
Subject: Control Arm for COVID-19 Trials

Dear Dr. Freire,

I wanted to share with you how Medidata - Acorn AI can provide to the COVID-19 Industry trials a Control Arm for COVID-19.

50 percent of the clinical trials currently being run on COVID-19 utilize the Medidata-Acorn AI platform. With this data that is being collected, we can provide a Synthetic Control Arm to be utilized by the industry as a whole.

Many of your **ACTIV** participants are current customers of Medidata platform.

Rather than having each separate company try to create a Synthetic Control Arm themselves, we have the data. Would it make sense for Medidata-Acorn AI to provide this Control Arm for use industry-wide?

I understand in following COVID-19 news that **the industry is struggling with having a Control Arm to compare trial data results to. We can provide this.**

I have attached a Fact Sheet on our Synthetic Control along with our presentation at ASCO on the actual use of our solution.

We want to help, please tell us how we can.

Continued Health,
Donna Locke

<image001.jpg>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 12/16/2020 9:45:37 PM
To: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
CC: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Rep. Wagner ACTIV constituent company

Thanks! Sorry forgot to include David!

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Wednesday, December 16, 2020 4:42 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Rep. Wagner ACTIV constituent company

Hi Ashley,

Yes, I can confirm they were received.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, December 16, 2020 4:13 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Rep. Wagner ACTIV constituent company

Hi Stacey,

Rep. Wagner's office and constituent, John Sastry would like to confirm whether or not the materials they submitted (please see attached) in response to their ACTIV/PI conversation were received?

Cc'ing David for awareness as a follow up to the war room discussion on Monday.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Friday, December 11, 2020 1:26 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Rep. Wagner ACTIV constituent company

Thanks!

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Friday, December 11, 2020 1:26 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Rep. Wagner ACTIV constituent company

Hi Ashley,

This one we just requested additional information from the PI this week. I am not sure if we have heard back. But in short the agent is still in review.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] | Mobile: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, December 11, 2020 1:22 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Rep. Wagner ACTIV constituent company

Hi Stacey,

Here comes another one! Please see below and feel free to let me know if I should continue to ask you about these or if I should send to Deloitte staff who are helping to track ACTIV submissions.

Thanks,
Ashley

From: Brand, Morgan (NIH/OD) [E] [b6]
Sent: Friday, December 11, 2020 1:11 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: Rep. Wagner ACTIV constituent company

Hi Ashley,

I hope this message finds you well. Rep. Wagner has a constituent (John Sastry) with a company (Akari Therapeutics) that has submitted an application through ACTIV. The company is eager to hear about their application. They have not provided an application number, but did provide their application (attached in case it's helpful). The staff's questions are:

- Generally, what is the timeline from when an application is submitted for ACTIV to initial outreach to the applicant?
- What is the general process for consideration?

Thanks for your help with this, please let me know if you have any questions.

Best,
Morgan

PS – I don't think we've met before, so... hello!

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 12/7/2020 5:05:48 PM
To: Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Wolinetz, Carrie (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1c655040d47346c7b04d7bc11a403ecb-wolinetzcd]
CC: Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freiremc]; Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]
Subject: RE: Happy Thanksgiving

Hi David,

I remember this discussion on more than one occasion during the ACTIV war room calls. Let me investigate which IC Directors were interested in meeting with CVS to learn more about their proposal and opportunities to work together. To ensure I understand, Michael Cohen is interested in collaborative work outside COVID trials – I hope this was made clear during the ICD discussions but we will find out.

If Carrie agrees, we should be able to take it from here to respond to Michael and work with IMOD to schedule the CVS meeting with ICDs.

Thanks,
Ashley

From: Wholley, David (FNIH) [T] <[b6]>
Sent: Monday, December 7, 2020 11:53 AM
To: Wolinetz, Carrie (NIH/OD) [E] [b6] Parker, Ashley (NIH/OD) [E] [b6]
Cc: Freire, Maria (FNIH) [T] <[b6]> Adam, Stacey (FNIH) [T] [b6]
Subject: FW: Happy Thanksgiving

Hi Carrie and Ashley:

As you know, CVS has been working with several NIH trials, including some ACTIV trials, on using their diagnostic and nursing services in order to provide referrals of COVID-19 positive patient or help with trial-related interventions. Shortly before Thanksgiving Michael Cohen reached out to FNIH via Stacey Adam to say that CVS has interest in providing these services, and perhaps others, more broadly to other NIH trials in other disease areas outside COVID. Via war room and other venues, I brought this request to Francis and Larry and asked how NIH wanted to handle it. Last I heard I thought there had been a discussion with the IC Directors and a conclusion reached to set up a call with interested ICs and CVS, but it appears from Michael's note below that no one from NIH has reached out. Rather than bother Francis or Larry directly I thought I would ask you what the status is, and whether you could respond directly to Michael's renewed request. Thanks, David

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, December 7, 2020 11:00 AM
To: Wholley, David (FNIH) [T] [b6]
Subject: FW: Happy Thanksgiving

FYI on CVS

Stacey J. Adam, PhD
Director, Cancer

APAR0000016094

Research Partnerships

Direct: [b6] | Mobile: [b6]

From: Cohen, Michael J [b6]
Sent: Monday, December 7, 2020 9:40 AM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Happy Thanksgiving

Hope you had a nice weekend. Just following up as no emails last week from those teams. Thank you for your help and championing CVS at NIH!

Best,
Michael
[b6]

Proprietary

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, November 30, 2020 12:32 PM
To: Cohen, Michael J [b6]
Subject: [EXTERNAL] RE: Happy Thanksgiving

**** External Email - Use Caution ****

Hi Michael,

Not that I know of, but I will keep you posted.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships
Direct: [b6] | Mobile: [b6]

From: Cohen, Michael J [b6]
Sent: Monday, November 30, 2020 12:29 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Happy Thanksgiving

Thank you greatly appreciated! Do you need anything from me?

Talk soon!

Best,
Michael
[b6]

Proprietary

APAR0000016094

From: Adam, Stacey (FNIH) [T] [b6]
Sent: Monday, November 30, 2020 12:27 PM
To: Cohen, Michael J [b6]
Subject: [EXTERNAL] RE: Happy Thanksgiving

**** External Email - Use Caution ****

Hi Michael,

I hope you had a great Thanksgiving, as well!

I am sorry that I did not follow up with you last week. The topic was discussed and there was general interest from many of the ICs. Dr. Collins staff is supposed to be reaching out to you to discuss further, as they wanted to be the ones to facilitate. If you don't hear by the end of the week, please let me know.

Thanks,
Stacey

Stacey J. Adam, PhD
Director, Cancer
Research Partnerships

Direct: [b6] Mobile: [b6]

From: Cohen, Michael J [b6]
Sent: Monday, November 30, 2020 12:17 PM
To: Adam, Stacey (FNIH) [T] [b6]
Subject: Happy Thanksgiving

Hi Stacey,

Hope you had a Happy Thanksgiving!

Any updates from last week regarding Dr. Collins and how we can potentially work together outside of COVID?

Michael J Cohen (he/him/his)
Director, Pharmaceutical Commercialization
CVS Clinical Trial Services

m [b6]
e [b6]



Proprietary

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APAR0000016094

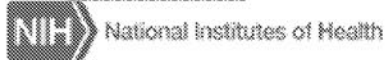
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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 7/27/2020 12:02:33 PM
To: Marks, Peter [b6]
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Peter,

Received – thank you.
Ashley

Ashley Parker, Ph.D.
Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)
Office of the Director | National Institutes of Health
Tel: [b6]



From: Marks, Peter [b6]
Sent: Monday, July 27, 2020 7:21 AM
To: Parker, Ashley (NIH/OD) [E] [b6] >
Subject: RE: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Ashley,

I will be able to clear my calendar and plan to join this meeting.

Best Regards,
Peter Marks

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, July 27, 2020 6:54 AM
To: [b6]
[b6] Ralph Sacco
[b6]
b6
Cc: Parker, Ashley S (NIH) [b6]; Tabak, Lawrence A (NIH) [b6]; Anderson, James M (NIH) [b6]; Austin, Christopher P (NIH) [b6]; Lane, Henry C (NIH) [b6]; Fauci, Anthony S (NIH) [b6]; Gibbons, Gary H (NIH) [b6]; Patterson, Amy (NIH) [b6]; Rutter, Joni L (NIH) [b6]; Kurilla, Michael G (NIH) [b6]; Woodcock, Janet [b6]; Disbrow, Gary (OS) [b6]; Freire, Maria C (NIH) [b6]; Wholley, David N (NIH) [b6]; Marks, Peter [b6]
Subject: URGENT: Convalescent plasma RCTs -- seeking a way to get to answers quickly

Dear Colleagues,

As the COVID-19 pandemic rages on in many parts of the world, it is absolutely urgent to obtain rigorous data on possible therapeutic interventions that could save lives. Convalescent plasma is one of the more promising interventions, but still lacks rigorous evidence from well-powered randomized controlled trials, though a number of such trials are underway. Janet Woodcock (who leads the therapeutics workstream for Operation Warp Speed) and I are

interested in convening all of the groups engaged in such RCTs, to see if there might be a way to accelerate progress – both for individual trials that might be sped up, or by well-designed meta-analyses.

Considering the importance of the issue, convening this group for a real time conversation is urgent. Accordingly, I am inviting you to join a **90-minute virtual meeting tomorrow, Tuesday July 28, starting at 11 AM EDT**. Zoom links will be sent shortly.

I would like each group to come prepared to give a quick synopsis of the status of your trial efforts – to include patient category, source of plasma (and whether the donor units are being assayed for antibody titer), current number of enrollees, timetable for completing enrollment, endpoints, timetable for expected read out of results. In some instances (such as the C3PO study) I have invited more than one investigator working on a collaborative trial, and I would appreciate the PIs agreeing about who is the best position to summarize that trial.

I apologize in advance for the ridiculously short notice! But as in all things COVID, the usual timetables for organizing meetings have gone out the window.

Please respond to Ashley Parker [b6] about your willingness to join the meeting.

Many thanks, Francis





Francis S. Collins, M.D., Ph.D.
Director, National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/24/2021 3:47:34 PM
To: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: List of all the members for all the WG and subgroups and subteams

Got it – thanks!

From: Melencio, Cheryl (FNIH) [T] [b6]
Sent: Wednesday, February 24, 2021 8:49 AM
To: Parker, Ashley (NIH/OD) [E] [b6] Brodd, Lauren (NIH/OD) [E] [b6]
Subject: FW: List of all the members for all the WG and subgroups and subteams

Here is Joe's list

Cheryl Melencio
Administrative Manager, Research Partnerships
Foundation for the National Institutes of Health
[b6]
fnih.org
11400 Rockville Pike Suite 600 North Bethesda, MD 20852
   



From: Menetski, Joseph (FNIH) [T] [b6]
Sent: Wednesday, February 24, 2021 8:29 AM
To: Melencio, Cheryl (FNIH) [T] [b6]
Subject: FW: List of all the members for all the WG and subgroups and subteams

See below, I think you have the Preclinical working group.

Joe

From: Hawk, Harrison <hhawk@deloitte.com>
Sent: Tuesday, February 23, 2021 7:19 PM
To: Menetski, Joseph (FNIH) [T] [b6] Connelly, Sarah <sconnelly@deloitte.com>
Subject: RE: List of all the members for all the WG and subgroups and subteams

Hi Joe,

Please find the complete list of ACTIV TRACE WG & Subgroup members. There is a main sheet that has the full list of WG members, and separate tabs for each subgroup. I am working to put together the same style spreadsheet for the full Preclinical WG. Please let me know if you have any feedback.

Best,
Harrison

From: Menetski, Joseph (FNIH) [T] { b6 }
Sent: Tuesday, February 23, 2021 3:16 PM
To: Hawk, Harrison <hhawk@deloitte.com>; Connelly, Sarah <sconnelly@deloitte.com>
Subject: [EXT] List of all the members for all the WG and subgroups and subteams

Dear Harrison and Sarah,

Do we have the lists done? I just got a request for this from NIH OD.

Joe

Joseph P. Menetski, Ph.D.
Associate Vice President, Research Partnerships
Foundation for the National Institutes of Health
{ b6 } fnih.org
11400 Rockville Pike, Suite 600, North Bethesda, MD 20852



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From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/23/2021 11:52:44 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: Re: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Lauren,

I've reached out to Stacey and Joe directly for this request, cc'ing you and Cheryl.

Hopefully they can clarify the NIAID roster and you can use this for updating the master excel file.

Have a good evening — thanks.

NIAID:

Alan Embry

Andrea Lerner

Ann Eakin

Clint Florence

Cliff Lane

Elizabeth Church

Elizabeth Higgs

Emily Erbeling

Hilary Marston

Jim Neaton

John Beigel

John Mascola

Judy Hewitt

Julie Ledgerwood

Manizhe Payton

Mary Marovich

Michael Proschan

Peter Kim

Randy Tressler

Sandra Sitar

Sarah Read

Seema Nayak

Ashley Parker, Ph.D.

Office of the Director | National Institutes of Health

Tel: [b6]

On Feb 23, 2021, at 6:15 PM, Parker, Ashley (NIH/OD) [E] [b6] wrote:

Sorry, what 5 members did you mention? I'm totally confused now.

I sent 22 names and asked to cross check with the additional list Cheryl will be sending which hasn't been received yet.

On Feb 23, 2021, at 5:01 PM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Was just confirming that you don't want to *add* any NIAID members (like the 5 I mentioned below that are involved with ACTIV but not on the NIAID award list)...I'm guessing the answer is no since the point of this is to limit, not add to, the list, but just wanted to make sure. The 17 names I sent you is a list of people that *both* appear on the ACTIV list as well as the NIAID award list. So that is the most complete list we have at the moment.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 4:28 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Emailing: Master and WG Email List for ACTIV rv19February2021

We are basically accounting for every NIAID staff member who participates in ACTIV based on the rosters.

Some of these names are on NIAID's original list and some were missing as you've indicated.

If confusing, let's chat about it when you're free.

Thanks,
Ashley

On Feb 23, 2021, at 4:04 PM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Just in case you get the info from Cheryl while I'm gone getting Mason (since I know you wanted to submit this today), I crossed checked what we have so far (names you listed below). Of the NIAID ACTIV members, these also appear on the NIAID award list:

Ann Eakin
Clint Florence
Cliff Lane
Elizabeth Church
Elizabeth Higgs
Emily Erbeling
Hilary Marston
John Beigel
John Mascola
Judy Hewitt
Manizhe Payton
Mary Marovich
Peter Kim
Randy Tressler
Sandra Sitar
Sarah Read
Seema Nayak

So in total we have 22 members from NIAID involved in ACTIV, with the above 17 on the NIAID list (5 do not appear on the list).

From: Brodd, Lauren (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 3:34 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV
rv19February2021

Just to confirm, you only want to know people that appear on NIAID awards list, correct? For example, Alan Embry is on your list below (so involved with ACTIV), but not on the NIAID awards list, so he should not be included in the final list?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 3:13 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV
rv19February2021

Below is what I have thus far from emails and Cheryl's vaccine list. Can you cross check these and add the NIAID names from the Tx clinical rosters/preclinical that Cheryl will be sending?

NIAID:
Alan Embry
Andrea Lerner
Ann Eakin
Clint Florence

Cliff Lane
Elizabeth Church
Elizabeth Higgs
Emily Erbeling
Hilary Marston
Jim Neaton
John Beigel
John Mascola
Judy Hewitt
Julie Ledgerwood
Manizhe Payton
Mary Marovich
Michael Proschan
Peter Kim
Randy Tressler
Sandra Sitar
Sarah Read
Seema Nayak

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 1:01 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV
rv19February2021

Yes

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 12:59 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV
rv19February2021

Do you have a min to chat?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:57 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV
rv19February2021

Looking at the attached email threads to the WG's (specially staff with NIAID emails), I am afraid members have been added to the WG's but maybe not shared with Cheryl?

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 12:46 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV
rv19February2021

I don't see Peter or Ann in the excel file. I also don't see Ann on the website for the Tx clinical WG: <https://www.nih.gov/research-training/medical-research-initiatives/activ/therapeutics-clinical-working-group?>

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 12:43 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Ann Eakin is on the Tx clinical WG – does she show up?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:41 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

I worked with Peter Kim on the ACTIV-2 request for machines and testing kits – is he missing?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:38 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Nancy Sullivan looks familiar too or am I mistaken? Seems she was on the vaccines WG?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:34 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

We are missing folks from NIAID – John Biegel leads ACTIV-5. Did Cheryl not add him to the roster?

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:57 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Ashley,

I went through the roster, and these people that are on the ACTIV roster and also on the NIAID list below:

Clint Florence
Judith Hewitt
Elizabeth Higgs
Emily Erbeling
Cliff Lane
Hilary Marston
John Mascola
Sarah Read
Seema Nayak
Manizhe Payton

Also just an FYI that there is one person (aside from Tony Fauci) that is on the ACTIV roster from NIAID but not on the list below: Michael Proschan.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:18 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Thanks!

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:17 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Yes will do and let you know this afternoon.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:00 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Lauren,

NIAID submitted the names below for the ACTIV award however NIH leadership has requested that this list be significantly cut down. Can you identify those who are currently listed on our ACTIV rosters from NIAID?

NIAID:

Adriana Andrade
Tia Morton
Ahsen Khan
Aileene Lewis
Akin Ojumu
Alisa Khomyanina
Alissa Burkey
Alkis Togias
Amy Adams
Andy Cherry
Ann Eakin
Aroussiak Bowen
Arzhang Cyrus Javan
Audria Crowder
Bariatu Smith
Beth Baseler
Betsey Herpin
Bobby Corno
Bola Adedeji
Callie Prassinis
Calvin Proffitt
Carmelle Norice-Tra
Carol Ostrye
Carol Worrell
Carole Andres
Charles Hackett
Charles Oluremi
Chase Sullivan
Christine Czarniecki
Claudia Baxter
Connie Suders
Conrad Mallia
Cynthia Osborne
Dan Curtin
Daniella Livnat
Dara Potter
Darlene Fitch
David Vallee
Denise Shelley
Dhawala Kovuri
Donna Germuga
Eileen Chang
Eileen Lake
Eileen Webster-Cissel
Elizabeth Church
Elizabeth Grace
Elizabeth Heredia
Elizabeth Higgs
Ellen Goldmuntz
Emily Erbelding
Erica Brittain
Esther Akpa
Grace Kelly

Grace Nissao
Greg Deye
Gregory Gendron
Guinevere Chun
Hamed Makou
Heather Deckert
Hilary Marston
Hyung Koo
Irene Rwakazina
Jackie Burns
Jaclyn Evans
Jake Stein
James McNamara
Jamila Aboulhab
Janet O'Brien
Janice Arega
Jen Sandrus
Jenna Briggs
Jennifer Cash
Jensen Gertz
Jerome Pierson
John Beigel
John Mascola
John Misasi
John Tierney
Jonathan Green
Jorge Mejia-Galvis
Josh Lorenzo
Joy Beeler
Judith Zuckerman
Jui Shah
Karen Reese
Katy Saliba
Keisha Johnson
Kelly Cahill
Kelly Parsons
Kevin Barrett
Kim Brookens
Larry Chen
Laura McNay
Leah MacDonald
Lei Huang
Liam Harmon
Linda Ehler
Lindsey Yeon
Lisa Giebeig
Lisa Hoopengardner
Lizanne Selthoffer
Lorraine Waring
Lynda Huber
Lyudmila Lyakh
Manizhe Payton
Marc Teitelbaum

Margarita Gomez
Mark Mishkin
Mark Robien
Martin Johnson
Martin McPhee
Mary Marovich
Mary Smolskis
Mary Wright
Maryam Jahromi
MaryAnne Luzar
Matthew Kirchoff
Maxwell Rajan
Meryna Manandhar
Mi Ha Kim
Michael Finn
Michael Galcik
Michael Welsh
Michelle Conan-Cibotti
Michelle Wildman
Molly Buehn
Nancy Bridges
Nancy Sullivan
Neelam Gulati
Odav Jallah
Onyinye Erundu
Ousmane Toure
Page Crew
Patrice Becker
Patricia Gottdiener
Peter Kim
Preston Holley
Randy Tressler
Ratna Sardana
Rebecca Mock
Rick Koup
Rob Palmer
Rona Siskind
Ruth Ebiasah
Sanaz Hamrah
Sandra Sitar
Sarah Read
Scott Garrand
Seema Nayak
Shamay Knox
Shane Ryan
Sharon Segal Raim
Shelly Simpson
Shere Billouin Frazier
Sindhu Gopalan
Sonia Gales
Stacy Kopka
Susan Vogel
Suzanne Dolney

Tammy Yokum
Teri Lewis
Theresa Engel
Thucuma Sise
Tseday Girma
Vanessa Eccard Koons
Victoria Wulah
Wade Green
William Erhardt
Yette Asfaw
Yin Li
Yvonne Jato
Swee Teo
Brian Madgey
Stanley Knight
Clint Florence
Judy Hewitt
Ann Eakin
Paula Bryant
Liliana Brown
Rick Sciotti
Mark Challberg
Mindy Davis
Greg Deye
Carl Dieffenbach
Cliff Lane

Thanks,
Ashley

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Friday, February 19, 2021 5:28 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV
rv19February2021

Thanks, and same to you!

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, February 19, 2021 5:26 PM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: Re: Emailing: Master and WG Email List for ACTIV
rv19February2021

Got it — thanks and have a good weekend!

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Feb 19, 2021, at 4:00 PM, Brodd, Lauren (NIH/OD) [E]

b6

wrote:

Hi Ashley,

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Thanks,

Lauren

-----Original Message-----

From: Melencio, Cheryl (FNIH) [T]

b6

Sent: Friday, February 19, 2021 3:48 PM

To: Parker, Ashley (NIH/OD) [E]

b6

Cc: Brodd, Lauren (NIH/OD) [E]

b6

Subject: Emailing: Master and WG Email List for ACTIV
rv19February2021

Hi Ashley

There have been a couple changes to the leadership team.

Andy Plump, Takeda has asked that Rajeev Venkayya attend the Leadership meetings in his place. Rajeev Venkayya, MD, President, Global Vaccine Business Unit, Takeda

Rachel Ramoni, VA has asked that Victoria Davey attend Leadership meetings in her place. Victoria Davey, PhD, MPH, Chief Research & Development Officer for Public Health and Epidemiology, U. S. Department of Veterans Affairs

I have updated the spread sheet.

Cheryl

Your message is ready to be sent with the following file or link attachments:

APAR0000011582

Master and WG Email List for ACTIV rv19February2021

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<Master and WG Email List for ACTIV
rv19February2021.xlsx>

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 2/23/2021 5:44:55 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

This isn't good because it signifies the list is not up to date.

From: Brodd, Lauren (NIH/OD) [E] { b6 }
Sent: Tuesday, February 23, 2021 12:44 PM
To: Parker, Ashley (NIH/OD) [E] { b6 }
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

I don't see John Biegel or Nancy Sullivan on our list or on Cheryl's most recent (attached)? I did a search for their last names in Cheryl's file, unless their last name isn't in their email address?

From: Parker, Ashley (NIH/OD) [E] { b6 }
Sent: Tuesday, February 23, 2021 12:38 PM
To: Brodd, Lauren (NIH/OD) [E] { b6 }
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Nancy Sullivan looks familiar too or am I mistaken? Seems she was on the vaccines WG?

From: Parker, Ashley (NIH/OD) [E]
Sent: Tuesday, February 23, 2021 12:34 PM
To: Brodd, Lauren (NIH/OD) [E] { b6 }
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

We are missing folks from NIAID – John Biegel leads ACTIV-5. Did Cheryl not add him to the roster?

From: Brodd, Lauren (NIH/OD) [E] { b6 }
Sent: Tuesday, February 23, 2021 11:57 AM
To: Parker, Ashley (NIH/OD) [E] { b6 }
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Ashley,

I went through the roster, and these people that are on the ACTIV roster and also on the NIAID list below:

Clint Florence
Judith Hewitt
Elizabeth Higgs
Emily Erbeling
Cliff Lane
Hilary Marston
John Mascola
Sarah Read
Seema Nayak
Manizhe Payton

Also just an FYI that there is one person (aside from Tony Fauci) that is on the ACTIV roster from NIAID but not on the list below: Michael Proschan.

Thanks,

Lauren

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:18 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Thanks!

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:17 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Yes will do and let you know this afternoon.

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, February 23, 2021 11:00 AM
To: Brodd, Lauren (NIH/OD) [E] [b6]
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Hi Lauren,

NIAID submitted the names below for the ACTIV award however NIH leadership has requested that this list be significantly cut down. Can you identify those who are currently listed on our ACTIV rosters from NIAID?

NIAID:

Adriana Andrade
Tia Morton
Ahsen Khan
Aileene Lewis
Akin Ojumu
Alisa Khomyanina
Alissa Burkey
Alkis Togias
Amy Adams
Andy Cherry
Ann Eakin
Aroussiak Bowen
Arzhang Cyrus Javan
Audria Crowder
Bariatu Smith
Beth Baseler

Betsey Herpin
Bobby Corno
Bola Adedeji
Callie Prassinis
Calvin Proffitt
Carmelle Norice-Tra
Carol Ostrye
Carol Worrell
Carole Andres
Charles Hackett
Charles Oluremi
Chase Sullivan
Christine Czarniecki
Claudia Baxter
Connie Suders
Conrad Mallia
Cynthia Osborne
Dan Curtin
Daniella Livnat
Dara Potter
Darlene Fitch
David Vallee
Denise Shelley
Dhawala Kovuri
Donna Germuga
Eileen Chang
Eileen Lake
Eileen Webster-Cissel
Elizabeth Church
Elizabeth Grace
Elizabeth Heredia
Elizabeth Higgs
Ellen Goldmuntz
Emily Erbeling
Erica Brittain
Esther Akpa
Grace Kelly
Grace Nissao
Greg Deye
Gregory Gendron
Guinevere Chun
Hamed Makou
Heather Deckert
Hilary Marston
Hyung Koo
Irene Rwakazina
Jackie Burns
Jaclyn Evans
Jake Stein
James McNamara
Jamila Aboulhab
Janet O'Brien
Janice Arega

Jen Sandrus
Jenna Briggs
Jennifer Cash
Jensen Gertz
Jerome Pierson
John Beigel
John Mascola
John Misasi
John Tierney
Jonathan Green
Jorge Mejia-Galvis
Josh Lorenzo
Joy Beeler
Judith Zuckerman
Jui Shah
Karen Reese
Katy Saliba
Keisha Johnson
Kelly Cahill
Kelly Parsons
Kevin Barrett
Kim Brookens
Larry Chen
Laura McNay
Leah MacDonald
Lei Huang
Liam Harmon
Linda Ehler
Lindsey Yeon
Lisa Giebeig
Lisa Hoopengardner
Lizanne Selthoffer
Lorraine Waring
Lynda Huber
Lyudmila Lyakh
Manizhe Payton
Marc Teitelbaum
Margarita Gomez
Mark Mishkin
Mark Robien
Martin Johnson
Martin McPhee
Mary Marovich
Mary Smolskis
Mary Wright
Maryam Jahromi
MaryAnne Luzar
Matthew Kirchoff
Maxwell Rajan
Meryna Manandhar
Mi Ha Kim
Michael Finn
Michael Galcik

Michael Welsh
Michelle Conan-Cibotti
Michelle Wildman
Molly Buehn
Nancy Bridges
Nancy Sullivan
Neelam Gulati
Odav Jallah
Onyinye Erundu
Ousmane Toure
Page Crew
Patrice Becker
Patricia Gottdiener
Peter Kim
Preston Holley
Randy Tressler
Ratna Sardana
Rebecca Mock
Rick Koup
Rob Palmer
Rona Siskind
Ruth Ebiasah
Sanaz Hamrah
Sandra Sitar
Sarah Read
Scott Garrand
Seema Nayak
Shamay Knox
Shane Ryan
Sharon Segal Raim
Shelly Simpson
Shere Billouin Frazier
Sindhu Gopalan
Sonia Gales
Stacy Kopka
Susan Vogel
Suzanne Dolney
Tammy Yokum
Teri Lewis
Theresa Engel
Thucuma Sise
Tseday Girma
Vanessa Eccard Koons
Victoria Wulah
Wade Green
William Erhardt
Yette Asfaw
Yin Li
Yvonne Jato
Swee Teo
Brian Madgey
Stanley Knight
Clint Florence

Judy Hewitt
Ann Eakin
Paula Bryant
Liliana Brown
Rick Sciotti
Mark Challberg
Mindy Davis
Greg Deye
Carl Dieffenbach
Cliff Lane

Thanks,
Ashley

From: Brodd, Lauren (NIH/OD) [E] [b6]
Sent: Friday, February 19, 2021 5:28 PM
To: Parker, Ashley (NIH/OD) [E] <[b6]>
Subject: RE: Emailing: Master and WG Email List for ACTIV rv19February2021

Thanks, and same to you!

From: Parker, Ashley (NIH/OD) [E] [b6]
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Subject: Re: Emailing: Master and WG Email List for ACTIV rv19February2021

Got it — thanks and have a good weekend!

Ashley Parker, Ph.D.
Office of the Director | National Institutes of Health
Tel: [b6]

On Feb 19, 2021, at 4:00 PM, Brodd, Lauren (NIH/OD) [E] [b6] wrote:

Hi Ashley,

I didn't respond to Cheryl, but just an FYI that I looked back over my emails and we had asked a few times to use our excel. I think for whatever reason she prefers using hers, which is fine (maybe it is easier for her purposes to just have the emails). I will just make sure to make the changes on our version too (there aren't a ton of changes anymore so I don't think that is an issue), and keep it up-to-date with complete information (titles, degrees, etc).

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I have updated the spread sheet.

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Sent: 2/23/2021 5:11:05 PM
To: Brodd, Lauren (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba665dea08e54171b3d6890c2518ddb9-leponelm]
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Beth Baseler
Betsey Herpin
Bobby Corno
Bola Adedeji
Callie Prassinis
Calvin Proffitt
Carmelle Norice-Tra
Carol Ostrye
Carol Worrell
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Eileen Chang
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Elizabeth Church
Elizabeth Grace
Elizabeth Heredia
Elizabeth Higgs
Ellen Goldmuntz
Emily Erbeling
Erica Brittain
Esther Akpa
Grace Kelly
Grace Nissao
Greg Deye
Gregory Gendron
Guinevere Chun
Hamed Makou
Heather Deckert
Hilary Marston
Hyung Koo
Irene Rwakazina
Jackie Burns
Jaclyn Evans
Jake Stein
James McNamara
Jamilia Aboulhab
Janet O'Brien
Janice Arega
Jen Sandrus
Jenna Briggs
Jennifer Cash
Jensen Gertz
Jerome Pierson
John Beigel
John Mascola
John Misasi
John Tierney
Jonathan Green
Jorge Mejia-Galvis
Josh Lorenzo
Joy Beeler
Judith Zuckerman
Jui Shah
Karen Reese
Katy Saliba
Keisha Johnson
Kelly Cahill
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Kevin Barrett
Kim Brookens
Larry Chen
Laura McNay

Leah MacDonald
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Lizanne Selthoffer
Lorraine Waring
Lynda Huber
Lyudmila Lyakh
Manizhe Payton
Marc Teitelbaum
Margarita Gomez
Mark Mishkin
Mark Robien
Martin Johnson
Martin McPhee
Mary Marovich
Mary Smolskis
Mary Wright
Maryam Jahromi
MaryAnne Luzar
Matthew Kirchoff
Maxwell Rajan
Meryna Manandhar
Mi Ha Kim
Michael Finn
Michael Galcik
Michael Welsh
Michelle Conan-Cibotti
Michelle Wildman
Molly Buehn
Nancy Bridges
Nancy Sullivan
Neelam Gulati
Odav Jallah
Onyinye Erundu
Ousmane Toure
Page Crew
Patrice Becker
Patricia Gottdiener
Peter Kim
Preston Holley
Randy Tressler
Ratna Sardana
Rebecca Mock
Rick Koup
Rob Palmer
Rona Siskind
Ruth Ebiasah
Sanaz Hamrah
Sandra Sitar

Sarah Read
Scott Garrand
Seema Nayak
Shamay Knox
Shane Ryan
Sharon Segal Raim
Shelly Simpson
Shere Billouin Frazier
Sindhu Gopalan
Sonia Gales
Stacy Kopka
Susan Vogel
Suzanne Dolney
Tammy Yokum
Teri Lewis
Theresa Engel
Thucuma Sise
Tseday Girma
Vanessa Eccard Koons
Victoria Wulah
Wade Green
William Erhardt
Yette Asfaw
Yin Li
Yvonne Jato
Swee Teo
Brian Madgey
Stanley Knight
Clint Florence
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Office of the Director | National Institutes of Health

Tel: [b6]

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Cc: Brodd, Lauren (NIH/OD) [E]

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Rachel Ramoni, VA has asked that Victoria Davey attend Leadership meetings in her place. Victoria Davey, PhD, MPH, Chief Research & Development Officer for Public Health and Epidemiology, U. S. Department of Veterans Affairs

I have updated the spread sheet.

Cheryl

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APAR0000011874

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Sent: 7/14/2020 7:21:23 PM
To: Santos, Michael (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab38cb6836de44e18ef4cc6952f65f80-santosmr]
CC: Tolman, Brett [btolman@deloitte.com]
Subject: RE: Harmonized Vaccine Trial Designs

Hi Mike,

This sound great – I know Dr. Collins has asked for this previously but hasn't raised since, hence my note to you versus bringing this up during the pre-EC call. Before the WG is set to close out, prior to July 31st would work for our purposes.

Thank so much,
Ashley

From: Santos, Michael (FNIH) [T] [b6]
Sent: Tuesday, July 14, 2020 2:34 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Tolman, Brett <btolman@deloitte.com>
Subject: RE: Harmonized Vaccine Trial Designs

Hi Ashley,

Yes, this comes up for me regularly as well. It would be great to do a protocol outline similar to what WHO has done and share that publicly. Unfortunately we've been told by CoVPN that's not possible yet, and the timeline is probably early August.

In the meantime, I think we could come up with a bullet point list of the areas of harmonization (with the details of what the actual harmonized approaches are). I can put that on our list to draft, and then CoVPN will need to sign off. Other than ASAP, is there a particular timeline we should target?

Thanks,
Mike

Michael Santos, PhD
Associate Vice President, Science | Foundation for the National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Tuesday, July 14, 2020 2:25 PM
To: Santos, Michael (FNIH) [T] [b6]
Subject: Harmonized Vaccine Trial Designs

Hi Mike,

The question of seeing the actual components that were agreed to be harmonized for vaccine trials has come up many times – do we have a document that outlines the harmonized components of the vaccine trials? We may use this information for the ACTIV webpage for public facing once approved.

Thank you,
Ashley

Ashley Parker, Ph.D.

Special Assistant to the NIH Director for Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV)

Office of the Director | National Institutes of Health

Tel: b6



National Institutes of Health

From: Parker, Ashley (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=306B2244466140FAA95AAAAFE06EBD70-PARKERAS]
Sent: 7/20/2020 5:37:58 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
Subject: RE: Hever Call 24th July

Here you go: [b6]

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, July 20, 2020 1:18 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Subject: RE: Hever Call 24th July

Can you track down an e-mail for Hal?

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 20, 2020 12:43 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: RE: Hever Call 24th July

Done! Friendly reminder to forward final slides to Hal.

Thanks,
Ashley

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Monday, July 20, 2020 12:24 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Hever Call 24th July

Looks good, fine to send (minus slide 9).

Tx, FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Monday, July 20, 2020 12:07 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: Adam, Stacey (FNIH) [T] [b6]
Subject: RE: Hever Call 24th July

Hi Francis,

Please see the attached PDF articles for pre-reads and the draft slides.

There are valid concerns for not sharing the nAbs readiness slide (back pocket slide 9) – Stacey indicated many of the companies being evaluated are at HEVER and some are not yet aware of their status. Slide 5 with the timeline and the colored boxes should be fine.

Once you clear, I will remove the back pocket slide and send materials to Jill and Morten.

Thanks,
Ashley

From: Parker, Ashley (NIH/OD) [E]
Sent: Monday, July 20, 2020 7:25 AM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Re: Hever Call 24th July

Got it — will do.

Thanks,
Ashley

On Jul 20, 2020, at 5:22 AM, Collins, Francis (NIH/OD) [E] [b6] wrote:

Hi Ashley,

For pre-reads, let's submit the CHIM paper and the Moderna phase 1 paper, both from NEJM.

For the ppts to be presented at the Hever meeting, I'd like to cull some visuals from last week's ACTIV ExComm meeting, but what I have is a pdf – so I'll need some help from you to capture these in the right format. Here's the order: 45, 2, 18, 21, 22, 28, 40. I need you to check with Stacey on slides 21 and 22, to see whether there is confidential information there that should not be shown to Hever. For slide 2 (the roster), please insert a better version that includes the entire Leadership – maybe an update from the July 1 meeting?

Please send me the version you can assemble from these materials so I can have a quick look before it goes to Jill.

Then I'll send it to Hal Barron with a note to give him a heads up about what I intend to cover.

Thanks, FC

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Wednesday, July 15, 2020 12:13 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Subject: Hever Call 24th July

Hi Francis,

Jill and Morten looped me into the Hever request to have your pre-reads submitted by Monday, 7/20. For pre-reads – would you like to share the CHIMs NEJM pub and give an update on the 4 CTs to launch soon which includes mAbs along with substantive updates to the other WGs?

The draft agenda has you and Hal Barron giving a 15 min update on ACTIV/mAb trials (7.5 mins each or will someone take the lead?). Attached are slides we submitted for the June 2nd Hever call, please let me know if you need assistance with pulling draft slides for your presentation. I assume you and Hal will work out the coordination if this hasn't happened already.

FYI – Janet is on the agenda following ACTIV to give an update on OWS non-funded trials – maybe a good idea to coordinate or at least share what you’re planning to cover before submitting to Hever?

Thanks,
Ashley

From: Jill Payne [b6]
Sent: Wednesday, July 15, 2020 10:00 AM
To: Parker, Ashley (NIH/OD) [E]; [b6]
Subject: FW: Hever Call 24th July

Ashley

Morten Sogaard has asked me to copy you into this, as you were so helpful with pre-reads last time. Pre-reads are required by the 20th July in time for circulation.

Many thanks

Kind regards

Jill Payne
On behalf of Hever

Email: [b6]
Cell: [b6]

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From: Jill Payne [b6]
Sent: 15 July 2020 11:56
To: [b6]
Cc: 'Wood, Gretchen (NIH/OD) [E]'; [b6]
Subject: Hever Call 24th July

Dear Dr Collins

Trevor Jones asked me to follow up with you regarding his email last week (see below)

Francis

Please find attached the draft Agenda for our telecon in 14 days time

Please will you confirm that you lead on the ACTIV mAb item

Also please can you arrange for someone to send a pre-read update on ACTIV to Jill for distribution before the event

Many thanks

Trevor

Is this OK with you?

Kind regards

Jill Payne
On behalf of Hever

Email: [REDACTED] **b6**
Cell: [REDACTED] **b6**

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From: Meltzer, Abbey (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C341D86CF7404A78AC8F852E698E5382-MELTZERAK]
Sent: 4/30/2020 3:09:03 PM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
CC: Melencio, Cheryl (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=279e14fa7428415bb86087d08b628e6f-melencioc]; Menetski, Joseph (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5001af52dc4a427ea3d34f1e072f8cb7-menetskijp]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]
Subject: RE: Corvid-19 Vaccine Project Concept

Thank you for the update, Ashley.

Best,
Abbey

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Thursday, April 30, 2020 10:56 AM
To: Meltzer, Abbey (FNIH) [T] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]
Subject: RE: Corvid-19 Vaccine Project Concept

Hi Abbey,

Thank you for sharing the request. Our NIH team is working with BARDA to develop the portal and we have training scheduled for this afternoon. I will let you know when this is up and running and David will likely share this information with the FNIH team as well.

Thanks,
Ashley

From: Meltzer, Abbey (FNIH) [T] [b6]
Sent: Thursday, April 30, 2020 10:18 AM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Melencio, Cheryl (FNIH) [T] [b6]; Menetski, Joseph (FNIH) [T] [b6]
Subject: FW: Corvid-19 Vaccine Project Concept

Hi Ashley,

Here is another request that we received related to ACTIV.

Just out of curiosity, do you have an update as to when a link to a portal/database will be up and running to collect this information?

Best,
Abbey

From: James C. Greenwood [b6]
Sent: 4/29/2020 8:03:27 PM
To: Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]
CC: McManus, Ayanna (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcf06de08ba845249b9b36ad216e237e-amcmanus]; Karen V. Cologne [b6]; Cartier Esham [b6]; Wholley, David (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd9e702fcf28414883d0b6996d677257-wholleyd]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]; DiLenge, Thomas (ACCF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a0adeb406de486c975a636c75b4b231-tdilenge.bi]
Subject: RE: [-EXTERNAL-] RE: BIO Analysis of COVID-19 Pipeline by category

Thanks, Francis. Hooray, indeed!

From: Collins, Francis (NIH/OD) [E] [b6]
Sent: Wednesday, April 29, 2020 3:54 PM
To: James C. Greenwood [b6]
Cc: McManus, Ayanna (NIH/OD) [E] [b6]; Karen V. Cologne [b6]; Cartier Esham [b6]; Wholley, David (FNIH) [T] <[b6]> Parker, Ashley (NIH/OD) [E] [b6]
Subject: [-EXTERNAL-] RE: BIO Analysis of COVID-19 Pipeline by category

Hi Jim,

Many thanks for your message. We are very glad to have this connection with BIO. Last week David Wholley of ACTIV connected with Danielle Friend and Cartier Esham from BIO and gave them a briefing on what we are doing with ACTIV. They shared information on BIO's inventory, which was very helpful. The ACTIV Clinical Therapeutics Working Group is actively prioritizing therapies for the next set of clinical trials, and BIO's input was much appreciated.

And now it looks as if therapeutic trials for advanced COVID-19 disease will have a new standard of care – hooray for today's positive RCT result!

Best, Francis

From: James C. Greenwood [b6]
Sent: Wednesday, April 29, 2020 12:12 PM
To: Collins, Francis (NIH/OD) [E] [b6]
Cc: McManus, Ayanna (NIH/OD) [E] [b6]; Karen V. Cologne [b6]; Cartier Esham [b6]
Subject: BIO Analysis of COVID-19 Pipeline by category

Dear Francis,

I read with interest your recent announcement of the ACTIV public-private partnership on accelerating COVID-19 treatments and vaccines – a subject that BIO has been intensely focused on over the past two months. In particular, BIO is working with our broad base of companies and several expert consultants to identify the most significant likely bottlenecks to speedy

clinical development and manufacturing scale-up for such products, as well as the capacities and resources that exist throughout the sector to solve those anticipated problems before they slow us down. As this project quickly progresses, we would be pleased to collaborate with NIH in terms of data sharing and execution of solutions if that is something of interest to you.

BIO also has been focused on helping government and NGO funding agencies better understand the unprecedented and rapidly growing pipeline of potential treatments and vaccines for COVID-19. We have more than 100 companies working on 300+ development programs, covering a wide range of potential approaches and technologies. To assist funders with a strategic review of this pipeline, we put together the attached slide deck summarizing the analysis done by our BIO Industry Analysis team, and explaining how this categorization and approach could aid the strategic and speedy review of funding proposals being made to government and other partners. We believe this information also could assist with ACTIV's strategic review and prioritization of potential assets. The Tracker that I refer to in these slides will be available soon on our BIO website and will be updated weekly.

Our goal is to be helpful to both the federal government and our member companies who wish to bring their innovative technologies to bear on solving this crisis. We stand ready to support any requests for assistance that you or your teams may have. Please feel free to reach out with any questions or comments.

Sincerely,

Jim Greenwood

Hon. James C. Greenwood
President and CEO
Biotechnology Innovation Organization (BIO)
Member of Congress, 1993-2005

1201 Maryland Avenue, SW – Suite 900
Washington, DC 20024

T **b6**
F +1.202.488.6307

b6

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/28/2020 10:43:34 PM
To: Li-fang Liang [REDACTED] b6
Subject: RE: ACTIV Partnership

Li—

Sorry for the delayed reply. Thank you for your interest in the ACTIV partnership to speed COVID-19 vaccine and treatment options. As you can imagine, the FNIH and NIH are receiving a large volume of requests similar to yours. To make sure that these requests are appropriately handled, the NIH is tracking and responding to all requests. I have forwarded this message to the NIH on your behalf. In addition I have sent it to our team that is considering agents that might be testing as part of ACTIV. That is the appropriate process for requests like yours right now.

Thanks,
David

From: Li-fang Liang [REDACTED] b6
Sent: Tuesday, April 28, 2020 2:33 PM
To: Wholley, David (FNIH) [T] [REDACTED] b6
Subject: Re: ACTIV Partnership

Dear Mr. Wholley,

I am checking back with you to find out whether there is a specific process or application for Fujifilm Pharmaceuticals to participate in the ACTIV partnership program.

Best regards,
Li

Li-fang Liang, PhD
Consultant
Fujifilm Pharmaceuticals, USA

On Thu, Apr 23, 2020 at 1:28 PM Li-fang Liang [REDACTED] b6 wrote:

Dear Mr. Wholley,

I am supporting Fujifilm Pharmaceuticals USA in their development of favipiravir, a broad-spectrum antiviral, as a treatment for COVID-19. Favipiravir is currently being tested against COVID-19 in clinical trials in the US, Japan, China and other countries. The drug has demonstrated activity against SARS-CoV-2 in *in vitro* assay and significantly better treatment effects were reported in favipiravir-treated COVID-19 patients in terms of disease progression and viral clearance when compared with control groups in clinical trials in China. The drug also has an extended safety database (~1500 subjects treated in the two US global Phase 3 influenza trials). Fujifilm Pharmaceuticals is interested in participating in the ACTIV partnership program and a colleague of mine from NIAID provided me with your contact information.

Could you let me know whether there is a specific process or application for participating in the ACTIV partnership program?

Best regards,
Li

Li-fang Liang, PhD
Consultant
Fujifilm Pharmaceuticals, USA

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From: Wholley, David (FNIH) [T] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CD9E702FCF28414883D0B6996D677257-WHOLLEYD]
Sent: 4/27/2020 2:07:22 PM
To: Jackie Quan [b6]; Collins, Francis (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=410e1ca313f44ced9938e50d2ff0b6c2-collinsf]; Freire, Maria (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8598d551d1d3455eaf14854c83f41d84-freirem]; Wolf-Rodda, Julie (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=89f0a08ab7224e0b9dc5a118ff336aff-wolfrodj]
CC: Adam, Stacey (FNIH) [T] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dcd875f0679648859e1cf101c0943414-adamsj4]; Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaaf06ebd70-parkeras]
Subject: RE: Karyopharm with NIH for COVID-19

Jackie,

Thank you for your interest in the ACTIV partnership to speed COVID-19 vaccine and treatment options. As you can imagine, the FNIH and NIH are receiving a large volume of requests similar to yours. To make sure that these requests are appropriately handled, the NIH is tracking and responding to all requests. I have forwarded this message to the appropriate contact for this at NIH on your behalf. In addition I have sent it to our team that is considering agents that might be testing as part of ACTIV so we make sure it is considered as part of their prioritization process.

Regards,
David Wholley

From: Jackie Quan [b6]
Sent: Monday, April 27, 2020 9:07 AM
To: Collins, Francis (NIH/OD) [E] [b6]; Freire, Maria (FNIH) [T] [b6]; Wholley, David (FNIH) [T] [b6]; Wolf-Rodda, Julie (FNIH) [T] [b6]
Subject: Karyopharm with NIH for COVID-19

Dear NIH Foundation Team,

Karyopharm is engaged in global, randomized studies to evaluate our small-molecule, oral drug selinexor in patients with advanced COVID-19 infections. These studies are based on substantial clinical and pre-clinical evidence, including new pre-clinical data in models of SARS-CoV-2, supporting a dual mechanism of anti-viral and anti-inflammatory activity through the inhibition of the nuclear export protein XPO1.

We welcome the opportunity to contribute to new research endeavors/collaborations with NIH Foundation in your ACTIV platform.

Key information about the use of selinexor to treat COVID-19 includes:

- Safety database of >3,000 patients treated with selinexor, a first-in-class oral inhibitor of XPO1 that is FDA approved under the commercial name XPOVIO® for the treatment of multiple myeloma.
- Extensive data providing evidence of dual anti-viral (including SARS-CoV-2) and anti-inflammatory activity, including reduction in cytokine storm that is deadly for patients with severe COVID-19 infections.
- Ample drug supply: oral tablets with long shelf life and suspension formulation.

The attached white paper contains more details on our therapeutic candidate and some of the key data.

We would like to make members of our executive team available to discuss how Karyopharm could made contributions by providing free drug for new research or other, as we strive to advance the public-private partnerships that are so critical to address the ongoing pandemic.

We hope to hear from you soon.

Best Regards,



Jackie Quan
Director, External Research Alliances Liaison
Karyopharm Therapeutics Inc.

85 Wells Avenue, Suite 210, Newton MA 02459
Karyopharm.com

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From: Pollock, Rachel (NIH/OD) [E] [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4887CB3513E242DFA7D2DF712DCC6D6A-POLLOCKRC]
Sent: 4/25/2020 1:37:57 AM
To: Parker, Ashley (NIH/OD) [E] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306b2244466140faa95aaaafe06ebd70-parkeras]
Subject: Re: novel approach to COVID-19 vaccine

Got this one and sent a response today. Thanks!

Rachel Pollock

O: [b6]
C: [b6]

From: Parker, Ashley (NIH/OD) [E] [b6]
Sent: Friday, April 24, 2020 9:36:43 PM
To: Pollock, Rachel (NIH/OD) [E] [b6]
Subject: FW: novel approach to COVID-19 vaccine

From: James, Stephanie (FNIH) [T] [b6]
Sent: Wednesday, April 22, 2020 8:48 PM
To: Parker, Ashley (NIH/OD) [E] [b6]
Cc: Wholley, David (FNIH) [T] [b6]
Subject: FW: novel approach to COVID-19 vaccine

Dear Ashley,

I am one of the FNIH folks involved in the ACTIV project. I understand you are collating all the unsolicited offers for help on the project, and am forwarding the one below for your files.

Best regards,
Stephanie

Stephanie James, PhD FASTMH
Senior Vice President, Science
Foundation for the National Institutes of Health
[b6]
www.fnih.org
11400 Rockville Pike Suite 600, North Bethesda, MD 20852

From: Caroline Kurtz [b6]
Sent: Wednesday, April 22, 2020 6:58 PM
To: James, Stephanie (FNIH) [T] [b6]
Cc: Michaela Dankova [b6]
Subject: novel approach to COVID-19 vaccine

Dear Stephanie,

I am reaching out to you as a contact on the FNIH site for information regarding grant opportunities for a COVID-19 vaccine. I lead programs at a small Biopharma company in Cambridge MA called Synlogic Inc (www.synlogictx.com),

APAR0000003559

and we are interested in applying for funding to support development of a vaccine for COVID-19 using our platform. We especially need support to test safety and efficacy of the vaccine in preclinical models under BSL3 conditions. Our proposal is as follows:

Synlogic Inc. proposes to develop a vaccine for the prevention of COVID19 utilizing its synthetic biology platform to engineer probiotic bacteria to express viral antigens and immune activators/adjuvants. This vaccine will be based on an engineered E. coli Nissle (EcN) bacterial strain that will express viral proteins from SARS-CoV2, the causative agent for COVID-19, and can be administered intranasally to induce protective immunity systemically and at mucosal surfaces. This vaccine can be manufactured in our GMP facilities to produce millions of doses from a single batch. As a lyophilized bacterial cell product, it is expected to have good room temperature stability.

We would be in preclinical development of this vaccine candidate, but already have an engineered E. coli Nissle strain currently in clinical trials for oncology, that can be rapidly adapted for this purpose. The grant would allow us to engineer the strain and test it in preclinical models to get a candidate for clinical studies. Our questions are:

1. Is this project of interest to FNIH? (we could provide an abstract if you need to read more detail to know)
2. Is grant funding available for small businesses?
3. Would a phone call facilitate determining level of interest for this work?
4. What is the process to apply?

Thanks very much for your help and if I should direct my inquiry elsewhere, please advise.

Sincerely,

Caroline Kurtz

Caroline Kurtz, PhD
SVP, Head of Portfolio Strategy and Product Development
Synlogic Inc
301 Binney Street, Suite 402
Cambridge MA, 02142

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